IN THE UNITED STATES DISTRICT COURT FOR THE

SOUTHERN DISTRICT OF WEST VIRGINIA, HUNTINGTON DIVISION

BEFORE THE HONORABLE ROBERT C. CHAMBERS, JUDGE

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CLAUDE R. KNIGHT and CLAUDIA STEVENS, individually and as personal representatives of the Estate of BETTY ERLENE KNIGHT, deceased,

Plaintiffs,

vs. No. 3:15-CV-06424

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,

Defendant.

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REPORTER'S TRANSCRIPT OF PROCEEDINGS

MOTIONS HEARING

TUESDAY, MAY 15, 2018, 1:25 P.M.

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HUNTINGTON, WEST VIRGINIA

TUESDAY, MAY 15, 2018, 1:25 P.M.

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THE COURT: Good afternoon.

MR. CHILDERS: Good afternoon.

MR. BELL: Good afternoon.

MR. HUDSON: Good afternoon, Your Honor.

THE COURT: All right. I understand everybody is here. We're ready to proceed?

MR. CHILDERS: Yes, sir.

MR. BELL: Yes, sir.

THE COURT: Well, I sent out an order late last week that described the sequence in which I thought it made sense to take up these motions.

So first I want to take up the defendant's motion for summary judgment. In the context of that, it seemed to me that a number of the issues raised in some of the motions in limine that the defense had filed were material to it. So I'm happy to trust that you have figured out how you want to present these things together so that they'll crystallize the arguments. Likewise with the plaintiff, you've got a cross motion for partial summary judgment, obviously responses to all of the motions in limine that I scheduled for hearing today.

So, with that, I'd just like to jump right into the

argument.

MR. HUDSON: Okay. Your Honor, given the fact that this case has been pending for a while, but we've never been here in front of Your Honor, would you like us at the podium?

How do you like --

THE COURT: Yes, I think it's better if you go to the podium. The acoustics in this room are not great, and in order for me to hear you and to make sure my Court Reporter can hear you, you really need to use the microphone, and it's probably easiest to use the podium.

MR. HUDSON: Okay. Thanks, Your Honor.

Okay. Your Honor, in connection --

THE COURT: And, I'm sorry, introduce yourself. I know you've made appearances for the record, but I don't know everyone.

MR. HUDSON: Thank you, Your Honor. My name is Eric Hudson. I'm from Memphis, Tennessee.

THE COURT: All right.

MR. HUDSON: And the way we had planned to structure this was I'm going to focus on summary judgment. And then in terms of the foreign labeling, the company core data sheet, the reversal agent and then Dr. Ashhab, the motion to exclude Dr. Ashhab, we will have different people speak to those as pertinent to summary judgment.

THE COURT: Okay. Fine.

MR. HUDSON: Okay. Great.

All right. So, Your Honor, we're here on Boehringer Ingelheim Pharmaceutical Inc.'s -- I'll call them BI -- motion for summary judgment. Ms. Knight is a woman who took Pradaxa for 18 months before the bleeding event that we're here about today. It's undisputed that she had her gastrointestinal bleed in the context of after having a bare metal stent placed and going on triple therapy of Plavix, aspirin and Pradaxa. And during that 30-day course of Plavix, she had her bleed and then ultimately went back on Pradaxa.

I want to address -- and we are moving for summary judgment on all the plaintiffs' counts. I'm going to focus my argument on failure to warn, and then I'll hit on design defect.

And starting with failure to warn, this argument would apply both to negligent failure to warn as it would to strict liability failure to warn, and both require proximate cause. And we cite these cases in our brief, Your Honor, but in West Virginia to prevail on a failure to warn claim, plaintiffs must show that a different warning would have changed the behavior in a manner which would have avoided the injury. That's the Tracy versus Cottrell case cited in our brief. And then later, the federal district court in West Virginia relied on that case in Meade versus Parsley to reinforce that standard of failure to warn.

It's not merely enough to show that an adequate warning would have changed the behavior. You've got to show that it would have changed the behavior in a manner which would have avoided the injury, which would have avoided Ms. Knight's bleed in the context of her triple therapy, ah, after her stent.

And the plaintiffs, in opposition to our motion, they point to Dawn MacFarland, M.D., who was the doctor at the prescribing -- at the office where Ms. Knight first received her prescription. And they point to some testimony from her to argue that, well, that would have changed the outcome. But if you look at what Dr. MacFarland testified to, we assert that's not the case.

And we're not discounting what Dr. MacFarland said. We're not suggesting that Dr. MacFarland's testimony ought to be construed in any light favorable to the moving party. We're saying that if you take Dr. MacFarland's testimony at its face value, that it's nothing more than speculation to conclude that anything in the record would have changed the outcome here.

And that's the standard we cite in -- on page 5 of our memo, Craft versus Boston Scientific Corp. and Thomas [verbatim] versus Potomac Electric Power, where, to avoid summary judgment, conclusory or speculative allegations are not enough. And that's really what you see when you look at

Dr. MacFarland's testimony.

THE COURT: Remind me what she said that the --

MR. HUDSON: Okay.

THE COURT: -- plaintiffs quoted in their response.

MR. HUDSON: Sure.

On page 8 of their brief, the plaintiffs cite Dr. MacFarland's testimony as follows:

Question: Okay. If the manufacturer had actually determined that there was a protocol you could use when you start a patient on Pradaxa, when you put them on the medication for a short period of time and then measure their plasma concentration so you can tailor the dose to make sure it's in a therapeutic range, would you use that protocol?

And she said yes.

If you look at that question, she says a protocol you could use when you start a patient on Pradaxa to tailor the dose. She was, Ms. Knight was started on Pradaxa 18 months before the bleed. To take that and leap to the conclusion that had Dr. MacFarland done whatever the plaintiffs suggest with respect to whatever different warning they may offer, it's speculation to suggest that that would have altered the outcome 18 months later.

THE COURT: Well, how is that speculative? I mean, I agree that the way the question is framed, it says when you start a patient on Pradaxa. Here we know she was on it for a

considerable period. We know that Dr. MacFarland continued that prescription. Dr. MacFarland continued to follow her. She was treated by other people, in and out of the hospital.

So if we agree for purposes of the question that a different warning would have been -- as plaintiff advocated, a stronger warning about all this combination of circumstances that this poor lady had --

MR. HUDSON: Uh-huh.

THE COURT: -- then why would we consider this speculative for Dr. MacFarland to be saying, yes, and if I had known about this warning during the course of treatment where I was continuing to prescribe this, especially when she was on the triple therapy, I would have followed that?

What is speculative about that?

MR. HUDSON: Well, one, that's not the question that was asked of her. But, two, presuming that there had been some warning that she took at the time, there is nothing -- there is nothing to suggest in the record that that kind of monitoring, if it was actually done, would have impacted the outcome, meaning Ms. Knight would not have had a bleed.

And that does tie in a little bit to Dr. Ashhab has an opinion that he thinks she was over-anticoagulated, and Mr. Richmond will talk a little more about that. But he refers to his testimony about her blood plasma level concentrations at the time of her bleed as a guesstimate.

THE COURT: Okay. I'll confess I've spent a lot of time with all of this.

MR. HUDSON: Sure.

THE COURT: But as is often the case for any of us, we get diverted to other things, and sometimes it's hard to --

MR. HUDSON: Understood.

THE COURT: -- put it all back together.

So I certainly could be wrong in saying this, but as I read Dr. Ashhab's testimony, and Dr. MacFarland's, it seemed to me that one could reasonably say that either or both of those doctors could testify that if there had been this stronger, clearer warning, more precise warning that plaintiff advocates, that the duty of care for the physician would have been to take that into consideration and tell Mrs. Knight we need to be monitoring your Pradaxa blood concentration.

So I guess what I'm sort of wondering is, in order to prove that it would have made a difference, as you characterized it, the proximate cause question, it could either come from testimony where Dr. MacFarland says, yes, it would have made a difference, I would have done this differently, I would have been checking her levels; or a physician could say that a reasonable physician would likely undertake that in order to conform to the standard of care.

MR. HUDSON: Yeah.

THE COURT: It seems to me either one would be enough

to at least get that issue to the jury.

Am I wrong?

MR. HUDSON: Respectfully, Your Honor, I would disagree, yes --

THE COURT: Okay.

MR. HUDSON: -- and on two grounds.

One, with respect to Dr. MacFarland, there is nothing in the record to suggest that that would have actually taken place. I mean, she just was never asked those types of questions. So to take that question that she was asked during the deposition -- and I want to go on because there is additional testimony from Dr. MacFarland. One of the questions was about plasma concentrations and the notion that, you know, well, maybe she didn't even know about this.

And she was asked:

Okay. Is that information that anybody from BI -- this is page 28 of the -- I'm sorry -- page 8 of the plaintiffs' brief. They cite to page 150 of Dr. MacFarland's deposition testimony via footnote, footnote 8 in their brief. But they're making an argument about the importance of plasma concentration in the context of failure to warn.

And the question is:

Okay. Is that information that anybody from BI has ever told you, that some of your patients may absorb this medication at a higher rate and, therefore, have a higher

concentration of it in their blood?

And Dr. MacFarland answered: I don't remember specifically being told that, but you can assume that or figure that out.

So you tie that into your question, Your Honor, and it reinforces the notion that Dr. MacFarland understood the notion that there are instances where patients may absorb more Pradaxa. And the Pradaxa label actually tells doctors you prescribe this based on renal function because your body renally clears the drug.

THE COURT: What about where she goes on, is then asked: And you don't have any way to measure whether it's her plasma concentration to know what the specific anticoagulant effect that it's having?

She says right.

And then as she goes on into the next page, there are several questions related to this, whether this information about the two-fold increase, as plaintiff characterized it, whether she had that. She didn't. Whether that would be important, she says perhaps.

MR. HUDSON: Uh-huh.

THE COURT: But, you know, perhaps means an equivocal yes.

And then knowing that there is this increase, if you have accurate information, which I take it means an accurate

warning quantifying this increased risk which is what plaintiff says ought to be the warning, would she take that into consideration in doing the risk benefit analysis?

She says yes.

If there was a way to measure the anticoagulant effect of Pradaxa, would you use it?

Sure.

If there was a way to tailor the dose to make sure it's within a therapeutic range, would you use it?

Yes.

And all those sound to me like the doctor saying, yes, if there had been a more complete warning, as plaintiff advocates --

MR. HUDSON: Uh-huh.

THE COURT: -- I would have taken advantage of that.

And if the complete warning is you ought to check levels, you ought to recognize there's a much greater risk, quantifiable risk for this type of patient with these combinations, would you consider that?

Yes.

So all those things tend to me to suggest that she's saying, yeah, if that warning had been there, as plaintiff advocates, and there had been a way to monitor plasma levels suggested by BI, I would have used it. I don't see how I can treat that as anything other than creating at least an issue

of fact for the jury.

MR. HUDSON: Yeah, and if I could respond to that because it sounds compelling. Okay. Well, just do the monitoring, everything is fine.

But that is the question. Is there anything nonspeculative to say that, okay, had there been a monitoring warning, and had Dr. MacFarland or Dr. Gunnalaugsson, anybody, monitored Ms. Knight's blood, would that have prevented the injury? And that's where it ties into Dr. Ashhab.

THE COURT: I agree.

MR. HUDSON: Okay. And so then --

THE COURT: I see that, too.

MR. HUDSON: Okay. And if you see that -- but there's --

THE COURT: Sure.

MR. HUDSON: So you take the warning, and if you say, okay, well, if that's going to create a nonspeculative warning, there's got to be that proximate cause step to get past summary judgment.

And I'll let Mr. Richmond talk about Dr. Ashhab in terms of why what he proposes to offer to say that warning would have prevented the injury and --

THE COURT: Well, and I guess to me -- you know, this is one reason I'm asking these questions is to see if I can make sure that I am analyzing this correctly.

MR. HUDSON: Sure.

THE COURT: So what we've kind of established is that Dr. MacFarland may well have testified sufficiently to say had this increased warning, more specific, quantified warning and this way to measure recommendation on how to monitor Pradaxa levels been available to me as the doctor, then I would have used it.

And then the question becomes, did the failure of it here contribute -- is there still causation in that plaintiff still needs to establish that she was over-anticoagulated?

MR. HUDSON: There's got to be some -- I didn't mean to interrupt.

THE COURT: No, go ahead.

MR. HUDSON: There's got to be a connection between the purported failure to warn and the injury.

THE COURT: Right.

So it is certainly arguable here that even if the jury believed that this more complete warning advocated by plaintiffs, and this way of monitoring plasma levels would have been demonstrated by the manufacturer, and Dr. MacFarland would have used those, that doesn't mean she was over-anticoagulated. But Dr. Ashhab says she was over-anticoagulated.

MR. HUDSON: Right.

THE COURT: So then I guess to me, then, that's really

maybe the more difficult question here.

And that is, does Dr. Ashhab -- and I think he's the only witness plaintiffs have about this -- have enough evidence that she was in fact over-anticoagulated to make all of the rest of this get to the jury?

MR. HUDSON: Right.

If you look at it that way -- and, Your Honor, I would assert that if you take -- I mean, it would be reasonable to take Dr. MacFarland's testimony and say based on that alone, even without getting to the additional component of Dr. Ashhab's testimony, it would be speculative to conclude that that would have made a difference.

THE COURT: Right.

MR. HUDSON: But if you take the next step and say, okay, I'm going to give them the benefit of the doubt on that one, then the Dr. Ashhab inquiry is, is what he purports to say, does that satisfy Daubert?

So -- and if that's where your inquiry is focused, then I'm going to -- I'll move on and let Mr. Richmond --

THE COURT: That would be fine.

MR. HUDSON: -- come back to that one, if that works.

Okay. I do want to also say, Your Honor, because, you know, there's been a focus on Dr. MacFarland in connection with the failure to warn claim, you know, we've got the added element where this is post-Karl, pre-legislative amendment.

THE COURT: Right.

MR. HUDSON: And there I think the record is pretty clear that there is nothing to indicate that Ms. Knight read or would have read these warnings. But you've got back-stopped against that the language of the medication guide, which is provided along with the medicine. And we attached that as Exhibit 9 to our opposition to plaintiffs' motion for summary judgment.

When you look at what the plaintiffs are saying in the context of all of their warnings, I mean, the medication guide tells patients you have a higher risk of bleeding if you take Pradaxa and are over the age of 75; if you have kidney problems; if you take other medications that increase your risk of bleeding, including Plavix.

And then the plaintiffs in their briefing make -- they say a lot about P-gp inhibitors. The medication guide addresses that, too, in general -- in lay terms. It says tell your doctor about all of the medications you take, including prescription and nonprescription medications. Some of your medications may affect the way Pradaxa works, and certain medications may increase your risk of bleeding.

So to the extent we're looking at the plaintiff herself, there's nothing in the record to suggest that any additional warning or action to her would have averted the harm.

THE COURT: Well, I do think it's clear that what plaintiffs are advocating here is that the warnings that accompanied the medication when she first started taking it were incomplete or inadequate. And that they've been pretty I think specific saying that BI had knowledge that people with this level of renal impairment have a specifically quantifiable increased risk, three times I think is what they say. That may be -- I mean, that's what they say, and they've got BI documents and some of the studies to back that up. I understand you've got defenses on some of that.

But basically they say severe renal problems, three times. Over age 80, two times greater. The European label saying that if you've got these conditions, not just that it's warning that there could be a bleeding complication, but stronger, clearer warnings that you shouldn't be on this, you shouldn't try this if you've got these other combination of medications and so forth.

So, you know, I think probably like the other courts where you folks have already blazed your trail a few times, I think I'm probably going to end up concluding that there's enough there to support the plaintiffs' claim to get to the jury that the warnings were inadequate given all of these circumstances, many of which are kind of unique to Ms. Knight because she had that combination of medical conditions and other medications and other risk factors.

MR. HUDSON: Okay. Then, Your Honor, I'll finish up on failure to warn given that we've still got to talk about Dr. Ashhab.

THE COURT: Right.

MR. HUDSON: And I'm sure you've caught this in going through this. This is a 75-milligram dosage. There is no lower dose of Pradaxa. And the 75-milligram dose was never approved in the European Union. It was approved by the FDA based on the FDA's -- excuse me -- own initiative to conduct modeling for people like Ms. Knight, who had renal function below a certain level.

So there are a lot of differences in this one, which are going to --

THE COURT: And I think I agree with the other courts that have said plaintiffs' warnings claim cannot include or rely upon the claim that a lower dose should have been available or provided.

MR. HUDSON: Yeah.

THE COURT: I think it's the completeness of the warning given these other relevant conditions and medications that she was on, whether she should have been taking it or not, not that the dosage was -- not that there was inadequate warning relative to the dosage amount.

MR. HUDSON: Understood. And I'll leave that because we are going to argue the foreign label.

THE COURT: Sure.

MR. HUDSON: Okay. Then I'll move on to design defect, then, if it's okay. Unless you have any questions I can address on failure to warn.

THE COURT: No.

MR. HUDSON: Okay. Well, let me back up.

One point on failure to warn, particularly -- and I'll come back, I guess, after plaintiffs argue their brief. But in the briefing on theirs, I think there was some back and forth on use defect. And, you know, we are arguing use defect is a strict liability failure to warn claim. That's the premise of our strict liability failure to warn motion.

In terms of design defect, Your Honor, I think you have probably seen the Chambers decision and the Boone decision. The Chambers decision is Exhibit 9 to our summary judgment motion. The Boone decision is Exhibit 6 to our opposition --

THE COURT: Well, all this is premised upon plaintiffs' claim that there was an alternative, safer way to manufacture Pradaxa by either making Pradaxa reversible by the common, readily available means in hospitals, I guess in theory sort of similar to warfarin where there are substances that can be given to patients that tend to counteract it immediately; or an alternative design for failing to come up with this so-called antidote, the Praxbind, that is here

today.

MR. HUDSON: I think --

THE COURT: And it seems to me that the cases, most of the cases -- and I haven't seen a lot of these, but you've cited I think several which stand for the basic proposition that courts refuse to consider a separate drug like Praxbind or the unavailability of a separate drug like Praxbind as a design defect for Pradaxa.

And about the only thing that I can recall plaintiffs cited in opposition to that would be Judge Fallon's rulings in some of the Xarelto cases. And in his case, as I understand it, he denied summary judgment on this issue and determined that there was evidence from the plaintiffs that the drug manufacturer -- I don't remember who it was now for Xarelto -- that there was evidence that the drug manufacturer had, prior to FDA approval of Xarelto, knowledge of how to manufacture this so-called antidote. And so I'm wondering why that same analysis wouldn't apply here.

I realize that here Praxbind was not developed and actually taken to FDA until after she died. But plaintiffs argue that they have evidence that it was considered, developed to an extent and developable before. And that once you started marketing Pradaxa, given that there were a large number of major bleeds reported, that that information was available to you and that, therefore, there was an alternative

design in that you could have developed this antidote prior to Pradaxa being approved by FDA and marketed.

MR. HUDSON: Yeah, and three points on that --

THE COURT: Okay.

MR. HUDSON: -- which we rely on for summary judgement and in response to what the plaintiffs are saying in their motion.

The first -- you asked first about if Judge Fallon, you know, said, well, maybe they could have developed it sooner. If you look at the Chambers opinion, Judge Land, on page 36 of that opinion, took the evidence on that in the summary judgment briefing and said -- and this is a quote from him.

There is no evidence that anyone knew that idarucizmab, which is the --

THE COURT: State it again. I didn't hear you very well.

MR. HUDSON: Sure.

He says there is no evidence that anyone knew that idarucizmab, which is the scientific name for Praxbind, that the idarucizmab antibody could reverse Pradaxa's anticoagulant effect until Dr. Van Ryn developed the idea in 2008.

THE COURT: In 2008?

MR. HUDSON: 2008.

The evidence demonstrates that Boehringer moved

expeditiously to get Praxbind approved. Simply put, no reasonable juror could conclude from the present record that Boehringer developed an antidote in 2003 and kept it in the freezer for 12 years while Pradaxa patients suffered fatal bleeding.

So Judge Land squarely addressed that when he said, no, that's just not going to fly. That is the kind of speculation that is not going to get a plaintiff past summary judgment.

THE COURT: And I take it you're comfortable saying that the evidence that was before Judge Land in the Chambers case is the same as the evidence that the plaintiffs have cited here?

MR. HUDSON: To the best of my knowledge, yes.

THE COURT: All right.

MR. HUDSON: And I haven't done a lot of online comparison, but to the best of my knowledge --

THE COURT: Well, you haven't seen plaintiffs argue that they've got something different here.

MR. HUDSON: No, I haven't.

So that's one, and that's -- but then you've got two more. One you've got, okay, what are the elements for West Virginia strict liability law? They cite, the plaintiffs cite Mullins versus Ethicon, all derived from Morningstar. Design is defective in that it renders the product not reasonably

safe, and the defect proximately caused the plaintiff's injury.

So, again, that's the element. Did the defect cause the injury? No. The absence of a reversal agent could not in any way be construed as causing Ms. Knight's bleeding.

THE COURT: And, you know, I will also confess I have some trouble keeping straight what's in the label, what's in the medication guide and when they changed.

But with respect to, I guess, the information available at the time she started, did the label say at that point there's no antidote or something to that effect?

MR. HUDSON: Yes.

THE COURT: All right. So plaintiffs couldn't really claim a warning defect based upon the lack of an available antidote because that's exactly what you warned them.

MR. HUDSON: Right.

THE COURT: Okay.

MR. HUDSON: And that comes in, you know, in a different context, too, in that Dr. Ashhab, the plaintiffs' expert, he acknowledged that the RE-LY clinical trial, which is the trial --

THE COURT: Right.

MR. HUDSON: -- where Pradaxa was tested, and it led to FDA approval, that was tested without an antidote.

And Dr. Ashhab acknowledges that, you know, Pradaxa

had a better safety profile with respect to stroke prevention and avoiding the risk of intracranial hemorrhage -- which is warfarin, one of the big side effects of warfarin -- but acknowledged a known risk of gastrointestinal bleeding.

And so, you know, this all comes back to the fact this is an anticoagulate preventing strokes, and doctors are prescribing it knowing that there are risks of bleeding.

THE COURT: Right.

MR. HUDSON: And these are doctors that know there is no reversal agent. They know it was examined against warfarin without a reversal agent, and they know even there they know the outcome data.

THE COURT: And that's even though warfarin apparently does have some versions of antidotes available to them?

MR. HUDSON: And, I mean, to be fair, this isn't in the record, but Vitamin K takes 12 to 24 hours to work. The half-life of Pradaxa in a person with good renal function is about 12 hours. So the notion that warfarin has an immediate acting reversal agent at the time of Ms. Knight's bleed is -- and plaintiffs aren't arguing that.

THE COURT: Okay.

MR. HUDSON: So that's the second, is did the defect cause the injury? And the answer is no. So the plaintiffs come back and say -- on that one they say, well, this is kind of like a continuing injury or crash worthiness type of

analysis.

THE COURT: Enhanced injury.

MR. HUDSON: Enhanced injury.

And they cite to the crashworthiness case, and that is a case where somebody has an automobile accident, and then something goes wrong with the components of the car, they can still recover because of product defects in the car. But we weren't able to find a single case applying that to the prescription medicine context.

And when you look at the preemption analysis -- because this is, I think, where it really comes home in terms of preemption. Because Bartlett and Mensing, if you look at those, they say if you've got a state law duty that conflicts with the federal law duty, that claim is going to be preempted. And if a court were to find that, well, there's a continuing injury duty here akin to the crashworthiness doctrine, what that does is that creates a state law duty that says if you've got this medicine with a warned-about risk and that risk happens, and a warned-about fact that there is no reversal agent and you don't have a reversal agent, you can recover for the failure to -- for not having the reversal agent sooner.

That's exactly what Buckman -- excuse me -- Bartlett and Mensing address. I mean, and that really kind of squares away the preemption target.

I haven't seen courts, for example, in the cases we cited, and even Judge Land's decision or Judge Moll's decision in Connecticut, they don't talk about the details of it. But when you think about what that means, and what the state law duty would be and whether that conflicts with the federal standard, which is you cannot market a prescription medicine until you have FDA approval, that's square preemption.

And so the plaintiffs --

THE COURT: I think I probably agree with you with respect to this issue about the lack of a reversal agent, but I don't think that this carries over to the warnings.

It does seem to me, from reading these cases -- and I am not nearly as conversant as you are, for sure. But it does seem to me that when you talk about a brand name manufacturer, the cases recognize that, first, they've got a fair amount of control and discretion over what to put in the label. So they could change the warnings without either getting FDA approval or being relatively clear that they're going to get it. So most courts I think have said you would have to show clear evidence that it wouldn't be approved, some standard like that.

So I think that's probably where I come out on this, too, that I don't think preemption is going to extend to the warnings that we discuss today. But perhaps that's not the case, that maybe there is preemption with respect to this lack

of a reversal agent even if I were to consider that somehow a product defect.

MR. HUDSON: Understood.

And, you know, Judge Land squarely addressed the product defect component as well on page 39 of the -- 39 and 40 of his opinion, and I'll leave the cite at that. But he said it's not a product defect, it's a different product.

THE COURT: Right.

MR. HUDSON: It did not cause the injury.

Let me make two more points if I could, Your Honor, and then -- because I think I understand where your questions lie.

In the briefing, you know, the plaintiffs, I think their position evolved a little bit ending with I think their reply brief in opposition to their motion for summary judgment, where they said that, well, you know, Boehringer really should have just developed Praxbind before it even got FDA approval. And that's not preempted because, you know, we're not saying you couldn't have done it. We're just saying you should have done it and gotten it all done at once.

And there are two cases I want to bring to the Court's attention on that. One is the Yates case in the Sixth Circuit.

THE COURT: What's the name of it?

MR. HUDSON: Yates, Y-A-T-E-S.

The cite is 808 F.3d 281, and the Sixth Circuit Court of Appeals squarely addressed that same argument, which is the never start selling rationale. The notion that, okay, well, it's not going to be preempted if you just wait, and you don't sell it. And the Sixth Circuit addressed that and said that for the same reason the Supreme Court rejected the stop selling rationale, i.e. if you don't have a reversal agent, you shouldn't have it on the market, the Sixth Circuit said we're not going to buy the don't start selling it until you have it rationale.

And then the other case I want to bring to the Court's attention is another anticoagulant, and these post-warfarin anticoagulants are often referred to as NOACs, new oral anticoagulants. You've got Pradaxa, you've got Xarelto. You've got another one called Eliquis, and the Southern District of New York has addressed some of the Eliquis litigation.

And I just -- the cite to the Eliquis case is UTTS versus Bristol Myers Squibb, 226 F.Supp.3d 166. And there the district court out of the Southern District of New York addressed the never stop selling rationale as well as in the context of a drug akin to Pradaxa and said, well, you shouldn't have sold it until you had a reversal agent. And the federal court there did the same thing.

THE COURT: Okay.

MR. HUDSON: Any questions, Your Honor?

THE COURT: No. Thank you.

MR. HUDSON: Okay.

THE COURT: All right. Did you envision having your colleagues address the motions in limine as part of your summary judgment?

MR. HUDSON: I think we were flexible.

Have you got a preference?

MR. RICHMOND: I have no preference, Your Honor.

I didn't know whether or not you wanted to hear from plaintiffs regarding their response to the motion for summary judgment or have me --

THE COURT: Well, why don't we go ahead and get all of yours laid out here first, and then we'll get their response.

MR. RICHMOND: Good afternoon, Your Honor. I'm Orlando Richmond. I go by Rod, R-O-D.

I'm going to talk about Dr. Ashhab. I noted the questions that Your Honor had about that and realize that you're familiar with a great deal of his testimony, but let me start with just a little bit of pertinent background with respect to Dr. Ashhab's testimony.

And that is that after about a year and a half in of Ms. Knight using Pradaxa, she had symptoms of a heart attack and had a heart catheterization. And at that time this triple therapy that has been discussed was then invoked to include

Plavix and a low dose aspirin, 81-milligram aspirin.

That becomes later as we talk about Dr. Ashhab's opinions and how he arrived --

THE COURT: Right.

MR. RICHMOND: -- at his discussion of the bleed that occurred in this case.

He really has two broad opinions that I want to talk about. Number one is his opinion that Ms. Knight was over-anticoagulated at the time of her bleed. That particular opinion encapsulates or involves a number of other important strands or assertions in the case. There's a lot that is packed in there. And then, secondly, that the bleed in May of 2013 contributed to Ms. Knight's heart attack several months later in September of 2013. He says some other things as well, Your Honor, but primarily those two points take care of his opinions.

With respect to the over-anticoagulation, that opinion is based almost solely on a lab test that was conducted when she went to the hospital for the bleed. You probably read about the aPTT test, and it measures the amount of time it takes for the blood to clot using a reagent, and it's measured in seconds. The test indicated 47 seconds, as I recall, or the test that he relies upon indicated 47 seconds.

And from that -- and this is where the problem is -- he guesstimates, according to his own language, or speculates

about what her coagulation status would have been either 24 or 36 hours earlier at a relevant time. And his opinion with respect to over-anticoagulation is tied up almost entirely in that leap of logic, speculation or guess.

It's important because he admits that the 47 seconds in and of itself is therapeutic.

THE COURT: Right.

MR. RICHMOND: And so then for him to reach his opinion, he reaches back to what he believes to be a relevant time. And what's important is that that's not based on any scientific analysis as such or any medical analysis that he describes for us. It's not based on any literature that he offers for us. And quite frankly, to his credit, he ultimately admits that it's guesstimation or speculation.

THE COURT: Well, as I recall, in his deposition he was then questioned about the chart that was part of the label. And he points out and I think he even I guess at the deposition put his little mark at 47 showing that that is what her aPTT level was at that particular moment.

And then that's -- he is using this chart by BI. And he's saying so if she's at 47, which is within the therapeutic range at this time, I know that she had a bleed, a significant bleed. That she hadn't had Pradaxa for so many hours, I can't remember whether he said 36 or 24 or how he equivocated about that, but he then talked about his knowledge of the half-life

of the medication and so forth.

And so I have to admit I'm a little bit confused by both sides when it comes to that chart and what it means and doesn't mean. But I thought he used that chart to show that, according to BI, when you take Pradaxa, and you're one of these different types of patients that result in, as I recall, four different lines on the chart, one of which is based upon your creatinine clearance or your renal testing, that when you take Pradaxa, you start off with an aPPT pretty high and then it goes down. And he said after 36 hours, according to that chart, your line comes down pretty close to where she purportedly was by this test.

MR. RICHMOND: True.

THE COURT: Okay. What's wrong with that?

MR. RICHMOND: Well, a couple things, Your Honor.

First of all, the aPTT does not measure blood plasma concentration.

THE COURT: Right.

MR. RICHMOND: It measures --

THE COURT: We'll talk about that for a minute, because I understand that I think.

But the plaintiffs cite in several places part of the literature and part of the studies perhaps in which basically BI says, well, an aPTT is not really designed to determine your level of Pradaxa. As they've cited in their documents

and their arguments, there is in this literature an indication that it can be helpful in guiding you.

And I wish I had a better grasp of some of this now. If you had asked me a week ago, I could have pointed this out better.

MR. RICHMOND: Yes.

THE COURT: But you know what I'm talking about?

MR. RICHMOND: I do, Your Honor.

THE COURT: So why is that general discussion about, even though limited, the value of an aPTT in monitoring anticoagulation helpful in determining whether, as a result of being on Pradaxa, you're in a therapeutic range?

MR. RICHMOND: Well, a couple things about that.

The expert that will really talk about that, as I understand it, is a Mr. Gosselin. Mr. Gosselin is a laboratory type, a gentleman who has spent much of his life in labs. I know that because I just left trial in Connecticut and heard him testify for a couple days.

So he's talked about this issue, and one of the things that he says is that the aPTT is not useful for determining where someone is with respect to blood plasma concentration. It can't tell you that someone is super therapeutic or where they are in that. And that's -- that's the testimony I expect that they'll offer in this case.

THE COURT: Well, let me stop you there. I mean, I

agree, and I think that's obviously valuable testimony for your side.

But, you know, Dr. Ashhab -- is it Ashhab? Is that how you pronounce it?

MR. RICHMOND: I pronounce it Ashhab, Your Honor.

THE COURT: Yeah. He doesn't purport to be relying upon Mr. Gosselin for his determination that there was over-anticoagulation, but instead he refers to the BI documents.

So I agree that Gosselin seems to contradict him, but the question is I don't think that --

MR. RICHMOND: Right. Yes.

THE COURT: -- eliminates Dr. Ashhab's testimony.

MR. RICHMOND: Yes, sir.

The difficulty with Dr. Ashhab's testimony is he's done two things. One, he's talked about what we know based on what the test is and the lines that he drew as you pointed out --

THE COURT: Right.

MR. RICHMOND: -- but he wants to go further.

He wants to tell you what he doesn't know, and that is --

THE COURT: Which is what her levels would have been earlier.

MR. RICHMOND: That's correct, Your Honor.

THE COURT: But why is that chart discounted as a basis of the doctor saying, if she's at this level 36 hours after her last dose according to the Pradaxa chart, when she takes her first dose and is on it, she's going to be up here at this higher level and, over that same course of time, it comes down into this range that is close to 37?

MR. RICHMOND: Because I don't think that he uses the chart in that way, not precisely in that way.

What he says is, if I know that she's at 47 seconds at 24 or 36 hours, then I assume that she was 80, 90, maybe even 100 at some hours earlier. And that -- that is the definition of speculation. 80, 90, 100? And finally he says, you know, I just don't know.

THE COURT: Okay. I recall that part of his testimony, but I guess honestly I think I probably lean towards saying that -- when he tries to be specific and say she's 80, 90 or 100, you know, 36 hours before, I agree, I think that's speculation. I think he admitted as much.

But I don't think that means that he is being too speculative to say that I know, based upon this level of 47 at the time, recognizing that she'd been off Pradaxa for this long, recognizing that when you start taking Pradaxa according to BI you get a higher aPTT level, and figuring in my clinical judgment that she had a severe or significant bleed in the gastrointestinal area, which he's familiar with, that he is

using his, I guess, medicine arts judgment to say that she must have been much, much higher when she was on Pradaxa.

So why is that not just within the realm of clinical judgment?

MR. RICHMOND: Because that's not what he testified.

THE COURT: Okay.

MR. RICHMOND: What he said is it's my guesstimate. It could have been, it may have been.

We don't have --

THE COURT: Well, if we're going to say that, I mean, that's what he says when you tried to pin him down on give me a number. Is it 80, is it 90, is it 100? But I think in fairness, as I read his testimony overall, I mean, I think he's providing a level of medical certainty in his opinion that she was excessively over-anticoagulated when she started this bleed, and he can't do more than guesstimate at what her aPTT level would have been at the very time the bleed started.

But it didn't seem to me to be a big leap to say -- for a doctor with skill in handling patients like this to say she's over-anticoagulated.

MR. RICHMOND: Your Honor, what we know is that he's a gastroenterologist. He did not offer up any particular expertise that would allow him to apply medical judgment. He certainly didn't articulate any. It's based on his extrapolation.

THE COURT: I think he even admitted -- did he admit that he doesn't even prescribe Pradaxa?

Is that right or am I --

MR. RICHMOND: I don't recall, but I wouldn't be surprised if he didn't given what he does.

THE COURT: One last little thing here since you've already addressed it.

Looking at the guide, the patient guide -- is this the patient guide? And we think this is what was in effect at this time she started on Pradaxa, where it talks about the 2.4 surgery and interventions. It instructs that there is going to be an invasive or surgical procedure. That increases the risk of bleeding, so you should delay or stop it. You should -- your risk of bleeding should be weighed against the urgency of intervention.

It says bleeding risk can be assessed by ecarin clotting time, and it says this is a better marker for the anticoagulant activity of Pradaxa than an aPTT and INR and the other. But if that is not available, the aPTT test provides an approximation of Pradaxa's anticoagulant activity.

So --

MR. RICHMOND: Which is --

THE COURT: -- you all said that the doctor could use an aPTT level --

MR. RICHMOND: Which is different from blood plasma

concentration.

THE COURT: Of Pradaxa.

MR. RICHMOND: Yes.

THE COURT: Oh, I agree. Sure, I understand that. We don't have that. If we had that, we wouldn't have this debate. It would either show a level that was above therapeutic or below or within therapeutic.

But that is talking about when you don't have -- I think that's an aPTT, which is not Pradaxa level. It's using the aPTT clotting time as an approximation for Pradaxa's anticoagulation effect.

MR. RICHMOND: That's right, Your Honor.

And I think that, again, the best we have is what his testimony is. And I can appreciate Your Honor saying that he must be applying the medical science to make that determination, except he didn't say that. What he said was it's a guesstimate. What he said was I don't know what it was.

THE COURT: Yeah, I do recall that. I was a bit troubled by this, that he said, well, she must have been over-anticoagulated because she developed a bleed.

MR. RICHMOND: That's the other thing I wanted to address. Obviously you could have a bleed when you're on an anticoagulant in therapeutic range.

THE COURT: Right.

MR. RICHMOND: And so then just because she has a bleed doesn't mean that she is over-anticoagulated, and that's a fallacy in his analysis as well.

The second broad opinion that he offers is that the bleed was contributory to the heart attack that occurs months later. Again, he is a gastroenterologist. There is nothing that he described regarding his own practice, his own experience, his own background or methodology that allows him to make that leap.

THE COURT: I'm going to be real curious to see how plaintiffs respond to that. Because about the only thing I saw anybody say was that after this bleed, she didn't bounce back, she didn't seem to get all the way better.

There were general references to her being in and out of hospitals, including a skilled nursing unit, between then and September. I don't think anybody disputes that she died of a heart attack, plaintiffs argue it is, but through Dr. Ashhab, he's testified that this bleed so weakened her that it contributed to her later heart failure.

MR. RICHMOND: But he doesn't unpack that for us.

THE COURT: Right.

MR. RICHMOND: I mean, there really is no discussion, no analysis whatsoever of that issue other than what Your Honor has pointed out, that she didn't bounce back, she wasn't doing well. But there is no medical analysis of that issue.

THE COURT: So I just got the pretrial order today.

MR. RICHMOND: Yes, sir.

THE COURT: I at least just looked at it today. It lists all of the witnesses.

With respect to plaintiffs, they've identified the children, Dr. Ashhab, and then two or three of their general experts. And then it lists as -- those are testifying live. And then it lists as testifying by deposition a long list of doctors, which include I think about everybody who treated her from the time she was hospitalized and got the stent through the bleed through her death. So that means everybody, you all at least, know exactly what those doctors are going to say because it's going to be reading their depositions.

Do any of them provide a clearer statement to connect this bleed episode with her later heart attack?

MR. RICHMOND: Your Honor, I gotta tell you, I don't know whether or not anybody does that.

MR. HUDSON: If I may?

THE COURT: Sure.

MR. HUDSON: I think we'll hear from the plaintiffs that Dr. Abdelgaber --

THE COURT: Right.

MR. HUDSON: -- her primary care after the -- at least after the bleed, maybe some before the bleed, his testimony was something to the effect of she never bounced back.

THE COURT: Okay. Did he go so far as to say she didn't bounce back, and her heart attack is proximately related to this bleed and the effect it had on her? Or did he just say she just didn't bounce back, and then she had a heart attack?

MR. HUDSON: It's the latter, Your Honor.

THE COURT: All right.

MR. RICHMOND: And of course, finally, Your Honor, there is no demonstration from Dr. Ashhab that this heart attack would not have occurred otherwise but for her use of Pradaxa, which is an important consideration in this matter.

THE COURT: Okay. Thank you, Mr. Richmond.

MR. RICHMOND: Thank you, Your Honor.

THE COURT: Who is next?

MR. IMBROSCIO: Good afternoon, Your Honor. Michael Imbroscio from Washington, D.C., although originally across the river in Ohio.

I'm going to talk about the motion in limine on foreign labeling. I'm going to focus on that. I was going to cover a little bit the plasma concentration motion. I feel that that's been covered. If you have any questions, I'm happy to answer. And I think what I would like to do in the foreign labeling is begin just with kind of bringing it all together, setting the stage.

Pradaxa was a real step forward in medical care, I

think we all agree, and there subsequently have been several other additional medicines, Eliquis and Xarelto. When Pradaxa came to the market for this indication, for SPAF, stroke prevention in atrial fibrillation, it was brought to market both in Europe and in the U.S.

THE COURT: At the same time?

MR. IMBROSCIO: At approximately the same time.

The U.S. was first --

THE COURT: What year was that that at least it started here?

MR. IMBROSCIO: In the U.S., October of 2010. It was approved in October of 2010 -- I'll come back to the details in a moment -- and then the following year, I don't have the exact month, it was approved in Europe.

And when the company studied the medicine in the RE-LY trial, they set up the various parameters of the clinical trial. And one of the parameters was that anyone whose renal function was below 30, creatinine clearance below 30, were excluded from the trial. They were not able to participate, and if they fell below, they were I think converted to warfarin.

So it was the company's position, given that Pradaxa is renally excreted, that if you had renal impairment below 30, the medicine should not -- should not be given.

And the company tested two doses in the RE-LY trial,

110 milligrams and 150 milligrams. So as part of the approval process, the company in the U.S. submitted two doses for approval, the 150-milligram dose and 110-milligram dose.

Ultimately the FDA came to the conclusion, based on the RE-LY data, that the 150-milligram dose would be approved, but not the 110. And their rationale, which is laid out pretty clearly both in the approval documentation, but also quite remarkably in the New England Journal of Medicine, is that even though the 110 had less bleeding than the 150, that on balance, weighing stroke protection more, the 150 was better.

And in the FDA's words, they did not want doctors in the U.S. playing it safe by giving the 110. You can imagine doctors saying I don't want to risk a bleed. Stroke is -- obviously that's God's will, but I don't want to be the one causing someone to bleed. And that was a very unique public health decision, one that frankly, you know, was so remarkable that they felt they needed to publish in the New England Journal of Medicine.

What the FDA did do, though, is they said we understand, Boehringer, you don't think anyone should take this medicine, whether 110 or 150, below a creatinine clearance of 30. We at the FDA think more people can benefit from this medicine. It was the FDA's idea that we should maybe do what they call a half-dose, the 75-milligram dose.

And we can figure out that half-dose based on the plasma information that was gathered during the RE-LY trial, so that a greater population of individuals, of Americans can be on this medicine and benefit from it.

That's a uniquely FDA U.S. decision. In other countries, the 75-milligram was -- is not approved for this indication.

It is approved in Europe for an orthopedic indication, a short-term orthopedic indication, but not --

THE COURT: Something other than AFib.

MR. IMBROSCIO: Exactly right. It is for primary prevention of VTEs, essentially clots.

So that, it's fair to say, is a very complicated regulatory history and interaction between really fundamentally different public health decisions made in the U.S. versus in Europe. Because in Europe, they did approve the 150 and the 110 and, as a function of approving the 110, had to put in place a whole range of criteria for when someone should be on the 150 and when someone should be on the 110.

To be clear, those criteria originally emanated from the company when they submitted the approval packages to both the U.S. and to Europe. In the U.S., when the FDA made the decision not to approve the 110, all of that criteria got stripped out of the U.S. label, all the reference to the 110 got stripped out of the U.S. label.

So, for instance, you know, in the European label, if you're of a certain age, if you're above 80, then you should be on the 110 presumptively. Obviously in the U.S. there is no 110-milligram, and so that has to come out. And what has resulted as a function of that is just a very different set of dosing guidelines in the U.S. versus in Europe.

And having been a part of the two trials that have occurred so far, I think it's fair to say that the essence, if not the principal argument the plaintiffs have made to the jury is the company doesn't tell U.S. doctors what they tell doctors over in Europe. Which we think is just fundamentally unfair and probably in many material respects preempted in the sense of how can we be punished for not saying in the U.S. what we can't say.

THE COURT: Well, what specifically do you understand plaintiffs complain is not said here that is said there?

MR. IMBROSCIO: Oh, let me see if I can -- it's a long laundry list.

You don't tell U.S. doctors that in Europe above 80 you should be using a lower dose.

THE COURT: All right. And that is in the European label?

MR. IMBROSCIO: That is the definition of when someone should be using the 110-milligram dose.

THE COURT: Okay.

MR. IMBROSCIO: That's one.

Number two, there are various sets of combinations of creatinine clearance and concomitant medications for which the 110-milligram dose is recommended in Europe and not in the U.S. So I think a creatinine clearance below 50 with certain concomitant medications, including perhaps aspirin.

THE COURT: So I gather, then, what you're saying is that in the European label, these additional, more specific warnings about over 80, severe renal, taken concomitantly with two different categories of drugs, all those things or at least some of these things are aimed at the 110 dosage.

MR. IMBROSCIO: Yeah, that's exactly right.

THE COURT: Okay. And does this label, does the European label provide some quantification of the increased risk to people over 80, to people with severe renal or et cetera from taking Pradaxa?

MR. IMBROSCIO: Yeah, the one thing that does come to mind is a concomitant use of aspirin.

THE COURT: Right.

MR. IMBROSCIO: There is a statement in the European label that says essentially it doubles the risk. The U.S. -- and that comes from the company's data, one aspect of the data. The U.S. affiliate of Boehringer submitted that language to the FDA, and the FDA struck it out and said, no, we don't want to say that.

There are probably a laundry list of items that I can probably submit that relate to this. We could just probably look at the closing argument of the plaintiffs in the last two trials, and they are spelled out in extraordinary detail.

And that is really our concern, Your Honor, is that I've been doing this for a long -- a lot of years, and I get confused on what exactly the situation -- what happens in the U.S. label. And when we get criticized for not saying, you know, in these terms -- this is probably a slide or probably from many statements from their closing argument -- they're not telling U.S. doctors what they tell European doctors, that, of course, has in its own prejudicial aspect to it whatsoever in addition. But we think that in this setting, where it all really comes down to this unique public health decision that the FDA made in the U.S., that those arguments about what is said in Europe, what is said in the core data sheet, which essentially tracks the worldwide labeling, it's just unfair to essentially be fighting against that.

They can attack the U.S. label, they can say it's inconsistent with the RE-LY data, whatever they want to say. But these arguments that, you know, you should have had essentially a 110 available, which is essentially what they are when you peel away the -- when you peel away the onion, we are being criticized for not having the 110 available. We don't think that's a viable argument.

THE COURT: Well, what does the foreign label say with respect, then, to people with severe renal impairment?

MR. IMBROSCIO: They're not allowed to use the medicine. Below 30, which is usually the definition of severe renal impairment, they are contraindicated. They are not allowed to use this medicine under any of those.

THE COURT: But that's not true in the United States.

MR. IMBROSCIO: No, because the FDA said we want the people below 30 to have the benefit of this medicine, so we're going to use a half dose, which is a dose that is not available for SPAF elsewhere, certainly not in Europe.

And that's what makes this case even more complicated, because the cases we've done so far are cases where the individual was on the 150-milligram dose. Here we've got the added wrinkle of Ms. Knight to be on the 75-milligram dose, which is even more sort of confounding as to what the heck to make of it because there is no equivalent even in Europe of the 75-milligram dose.

THE COURT: Okay.

MR. IMBROSCIO: And so -- and I think that also plays into what Mr. Richmond said, which is this notion of anticoagulation. Whether there is evidence of the plaintiff being anti -- over-anticoagulated, excuse me, is even more speculative because it's literally a half dose. It would be one argument if the person is on the 150-milligram dose, an

argument about being over-anticoagulated.

By definition -- as I understand it, Ms. Knight's renal function was right around 30, I think it was maybe 34, a little higher at the time of admission. There would be no suggestion -- I don't know if you can get any expert to say this, that with a renal function of this amount, you would expect a person to be over-anticoagulated on a half dose, on a 75-milligram dose. I think they need that evidence to get over the next step.

And our view is substantively it should not be in. But certainly as a part of the trial in this case, the evidence of the foreign labeling should not come in, and we've cited in our brief the dozens of cases where the courts have reached that decision. We would ask that in this case as well.

THE COURT: Okay. Thank you.

MR. IMBROSCIO: Thank you, Your Honor.

THE COURT: All right. Does that complete the defense presentation?

MR. HUDSON: Yes, Your Honor.

You had reversal agent on the list of items, but given the discussions today, we'll leave that --

THE COURT: All right.

MR. HUDSON: -- and rely on the papers.

THE COURT: All right. Great.

We're going to take a quick recess and then let plaintiffs respond.

THE COURT SECURITY OFFICER: All rise. This honorable court will be in recess.

(Recess taken.)

THE COURT: All right. Ready?

MR. CHILDERS: Yes, Your Honor.

Good afternoon, Your Honor. I am Andy Childers on before of the plaintiffs in this case.

THE COURT: Welcome.

MR. CHILDERS: I'm not sure how you would like me to start or --

THE COURT: Well, at the beginning.

MR. CHILDERS: Okay. Fair enough. Fair enough.

I believe the argument from counsel -- and I'm going to do all of the argument, so I don't have to sit down. So any questions you have, you just let me know.

THE COURT: And Harry is going to be shouting things to you.

MR. CHILDERS: He may. He may hand stuff to me.

The first issue that was argued was failure to warn, and what was described to the Court was the failure to warn being simply that there was a lack of information in the label that a higher plasma concentration of Pradaxa leads to higher bleeds. That is a half portion of the failure to warn.

THE COURT: Okay.

MR. CHILDERS: There's a second portion to the failure to warn, and that is that at the time Ms. Knight started Pradaxa, the label did not tell her or her physicians that if a patient like her, who had severe renal impairment, was also taking a P-gp inhibitor medication, of which she was taking two at the time, they shouldn't take Pradaxa.

After Ms. Knight --

THE COURT: Say that again just to help me make notes to keep it clear.

MR. CHILDERS: Yes, sir.

Neither the label nor the medication guide --

THE COURT: At the time it was originally prescribed to her --

MR. CHILDERS: That is correct.

THE COURT: -- failed to tell the patient or the doctor --

MR. CHILDERS: That a patient with severe renal impairment, who is also taking a P-gp inhibitor medication -- she was on two of them. One is called Coreg, which is a heart medication, and the other is called Omeprazole, which is a proton pump inhibitor.

After she had been on Pradaxa for a short period of time, the manufacturer changed the label and added that information, but never sent a Dear Doctor letter to her

prescriber, never altered the patient medication guide.

THE COURT: When did they change it?

MR. CHILDERS: I believe it was within a month or two of her starting the drug.

And the testimony from Dr. Ashhab was that they failed to warn her physician, because when they made this significant change to the label, they did not notify her that that change had been made. And if that change had been made -- I'm sorry. If she had been made aware of that change, she would have known to stop Pradaxa or switch to a different anticoagulant for a patient who is on P-gp inhibitors.

So --

THE COURT: So the plaintiff -- or the defendant, rather, maintained the argument that there is no evidence that the patient -- and in the absence of this intermediary doctrine for this limited time frame in West Virginia, the duty is defined by what the patient should know. But there's no evidence that the patient did anything.

MR. CHILDERS: That's incorrect.

Her son and daughter were asked, I believe at deposition, did she read the information that was provided generally in medications, and they said they thought when she got them, she read them. Meaning when you go to the pharmacy, and they give you printouts, did she read them? And they said it was their belief that if she got it, she would have read

it.

THE COURT: So you contend the inference is that she would have read it at the time.

MR. CHILDERS: Correct.

THE COURT: But then when it changed, it's still in the same package, isn't it, the --

MR. CHILDERS: Well, the patient medication guide to this day doesn't tell patients like her, if you have severe renal impairment, and you're on one of -- this particular type of drug, the P-gp inhibitor, you shouldn't take Pradaxa. To this day it doesn't say that.

What it says is let your doctor know what medicines you're on. The same doctor prescribed her the Pradaxa as prescribed her the P-gp inhibitors. That didn't change.

THE COURT: So when you talked about the label -- was it the label that changed --

MR. CHILDERS: Yes, sir.

THE COURT: -- a month later?

MR. CHILDERS: Yes, sir.

THE COURT: So you're saying even when the label changed, it really didn't communicate fully that when you've got this combination, severe renal problems, and you're on these other drugs, you shouldn't be taking Pradaxa?

MR. CHILDERS: Correct.

It's not just be careful, you might bleed, it's you

shouldn't take it.

THE COURT: Right.

MR. CHILDERS: That's a very different warning than you are at an increased risk of bleed.

And the testimony at trial from Dr. Ashhab will be clearly if any doctor knew that information, they would stop the patient from taking that drug. And if that had happened, more likely than not, she wouldn't have had her bleed at all because she wouldn't have been on Pradaxa.

And when I asked if she would have just as likely had the bleed had she been on warfarin, the response from -- which is an alternative anticoagulant drug that she had been on previously, the response from Dr. Ashhab, which is consistent with the data from the defendant, is she had 50-percent higher increased risk of bleed on Pradaxa. So it's more likely than not that she would not have bled at the same time had she been on warfarin because the chance of her bleed was less likely. And that's in the record as well, Your Honor, and in his testimony.

THE COURT: Okay.

MR. CHILDERS: So there are two issues with the failure to warn, not just one. I wanted to make sure that was clear.

I think Your Honor touched -- picked up on right away that the patient medication guide that is given to the patient

doesn't quantify any risk whatsoever. It doesn't tell a patient any specific type of medication they might be on that may increase the risk other than saying, if you're on aspirin or on Plavix or on chronic use of an NSAID drug, a non-steroidal anti-inflammatory drug, that could increase your risk.

Again, it doesn't quantify it, though. It doesn't tell the patient the information that the company knows about how much that will increase the risk.

THE COURT: And what do you contend is the information the company knew that they should have put in this patient medication guide?

MR. CHILDERS: It's the information that is contained -- I'm glad you asked that because the last argument we had was foreign labeling and the company core data sheet, the company asking you not to let us show that to the jury.

That very information is contained in both of those documents. In the --

THE COURT: And what is that specific information?

MR. CHILDERS: The specific information is if you're on aspirin -- there are two doses of aspirin that patients take for maintenance of heart issues, 81 milligrams and 325 milligrams. If you're on the 81-milligram dose, the risk of bleed goes up by 50 percent. If you're on the 325-milligram dose, it doubles.

If you are taking Plavix, your risk of bleed doubles. If you are taking a chronic NSAID -- or excuse me -- taking an NSAID chronically, meaning you don't just take it every now and then for a headache, if you take it every day, your risk of bleed is increased by 50 percent.

THE COURT: So you're saying that quantification is adopted by BI in the company core safety sheet, and then did you also say in the European label?

MR. CHILDERS: That is correct, Your Honor.

THE COURT: Okay.

MR. CHILDERS: That information is contained in --

THE COURT: So you think that those two documents should each come in as proof of knowledge and notice to the defendant of those facts, those facts being the specifically quantifiable increased risk under certain co-medications.

MR. CHILDERS: I do. And I believe they should come in for other reasons I'm happy to tell you about right now if you'd like.

THE COURT: Okay.

MR. CHILDERS: One of the things that plaintiffs have to prove for strict liability here is alternative feasible -- feasible alternative design.

THE COURT: Okay.

MR. CHILDERS: What better evidence is there of an alternative feasible design than the label that this company

actually gives to doctors in the rest of the world?

THE COURT: And you're talking about a feasible alternative design in the label?

MR. CHILDERS: Yes, sir.

THE COURT: Not the product.

MR. CHILDERS: Correct, correct, the warning.

And in addition to that, the foreign label also contains specific information telling physicians how to measure Pradaxa levels.

As you've heard, we don't know Ms. Knight's Pradaxa level. The reason for that is physicians in the United States are not told how to directly measure the Pradaxa level. Physicians in the foreign label are told how to do that, what tests to use. And not only that, they are told what levels of Pradaxa in a patient's blood mean that patients have an increased risk of bleed.

So those are two additional pieces of information that are not included in the U.S. label, that have never been --

THE COURT: And at what point were they included in either the company core data sheet or the European label?

MR. CHILDERS: I don't believe the coagulation test information about the actual Pradaxa blood level is in the company core data sheet, but it has been in the foreign label since the beginning of that label being in existence to my knowledge, at least prior to the time that Ms. Knight took the

drug.

I don't --

THE COURT: Prior to her prescription?

MR. CHILDERS: Absolutely.

As well as telling physicians specifically to use a test, and the test you'll hear is called dTT or diluted thrombin time. That's a test that can be performed by labs in the United States. Quest and LabCorp, which I'm sure you've heard of -- if you go to physicians' offices, you see their boxes -- they can perform that test. Physicians in the U.S. to this day are still not told that that test to measure the Pradaxa level can be performed by those labs.

So that information, again, is in the foreign labels, and plaintiffs would use that to show knowledge on the company's behalf that there's a way to measure this Pradaxa level, and there's a way to know if it's too high, and that physicians and patients in West Virginia should be told that.

THE COURT: How do you decide if it's too high?

MR. CHILDERS: It's a specific finding, over 200 --

THE COURT: Okay.

MR. CHILDERS: -- nanograms per milliliter, Your Honor.

THE COURT: All right. So BI says in their own documents --

MR. CHILDERS: Correct.

THE COURT: -- that if you measure a Pradaxa concentration level that exceeds 200 units, you've got too much.

MR. CHILDERS: They don't say it's too high. What they say to the physician is that that means the patient is at an increased risk of bleed, and then it is up to the physician to decide how to deal with that.

THE COURT: Okay.

MR. CHILDERS: So what they are giving is here's the information. Physician, you use your clinical judgment. That information is not given to physicians here, it wasn't given to Ms. Knight's physicians, and it certainly wasn't given to Ms. Knight herself.

THE COURT: Okay.

MR. CHILDERS: So I believe for those reasons alone, the alternative feasible design and also the information going to knowledge should show that the foreign labels should come in.

The fact that there is no one --

THE COURT: And I gather that you agree that it would be unhelpful and confusing if you were to try to discuss or provide evidence in more detail about the European labeling regime, how things are done over there, requirements?

MR. CHILDERS: We have no intent of getting into any of that.

And the fact that there's a 110-milligram dose, that's a higher dose than Ms. Knight was on. There is no reason we would argue she should have been on a higher dose. Obviously we believe the 75-milligram dose was too high for her during the time she was on it, and that was why she had this bleed. So any argument that the 150 and the 110 dose in Europe are somehow going to have interplay here is not the case. She was not on a dose that should have -- she couldn't have gotten a lower dose.

What we're saying is, if her physician had been told you can measure the level, you can see that it's too high, then the physician would have known this wasn't the right drug for her. And her physician had three or four other choices to put her on besides Pradaxa at that point.

THE COURT: Well, as I understand the defendant's argument, at least part of it, it's that the European label is dictated by the fact that they allowed a 110 and a 150 dose. And that if it's a 110 dose, then there are these certain risks. But are they -- I'm trying to think how I can phrase this and make sense out of it.

So when the European label warns of these increased risks, is it based upon the fact that it's a 110 dose?

MR. CHILDERS: No. It's in the information for the 150- and the 110- and the 75-milligram dose in Europe. There is a 75-milligram dose there, just not for AFib.

What they tell physicians is the same information. Some patients are going to potentially have higher levels of Pradaxa, these are some of the reasons why they may have it, and here's how you can test for it, and here's how you can know if it's too high.

THE COURT: So it's not statements that are based on the assumption that you're taking at least 110?

MR. CHILDERS: No, sir. It's based on plasma concentration in the blood regardless of what dose you take.

THE COURT: Okay.

MR. CHILDERS: And the information given that I believe Mr. Imbroscio was talking about was, if you're on the 150 -- or if you are over 80, you just shouldn't take the 150. That's too much for you anywhere else in the world except for the United States. That's not really at issue here because Ms. Knight was never on the 150-milligram dose.

THE COURT: I think I've got it.

MR. CHILDERS: Okay. On the issue of proximate cause, in our response, Your Honor, to the defendant's motion for summary judgment on page 5, we have cited the information that Dr. Ashhab relied on for his opinion that Ms. Knight was over-anticoagulated at the time of her bleed, which included the aPTT level, which was 36 hours after her last dose. And he explains that's three half-lifes of the drug, meaning it's half gone, half gone again, and half gone again at that point.

And, yes, he's using aPTT, but that's the information the drug company label tells him to use to estimate that.

THE COURT: Now we're talking back to this chart?

MR. CHILDERS: Well, the chart -- I can get to that chart if you'd like, Your Honor.

THE COURT: Okay.

MR. CHILDERS: He didn't rely on that chart for his opinions. He was shown that chart at his deposition and said I can look at it, and I can see this is where she would have been. And I can also tell you three half-lifes have gone away from the drug at this point, so that makes me believe that she was over-anticoagulated.

And, yeah, I can't give you a specific number. You're right, he would have to guess. Anyone would have to guess to extrapolate a specific number for a patient. But he knew it was at least three half-lifes higher than it had been at the time it was measured. And at the time it was measured, it was over the normal range for aPTT.

THE COURT: 47 is over?

MR. CHILDERS: 47 is outside the normal range for aPTT. Doesn't mean at 47 a patient is over-anticoagulated, but at that point in time she hadn't taken the drug for 36 hours.

Now interestingly enough, Your Honor -- and this is included in our response to -- in fact, I think it's our

response to defendant's motion in limine No. 6 about plasma concentrations.

THE COURT: Yeah.

MR. CHILDERS: Just two weeks ago, the defendant's own scientists published a new paper. And in that paper, there's a chart on page 12 of our response, it's document 81, where they actually finally looked at patients like Ms. Knight who had severe renal impairment, who were taking the 75-milligram dose, and they looked at what the aPTT spread is for those patients.

And if you look at it, they are all around 50 going up to plasma concentrations as high as 700 nanograms per milliliter, which is clearly way higher than 200 nanograms per milliliter. Had this information been available at the time Dr. Ashhab was formulating his opinions, I'm certain he would have relied on it, and it supports exactly what he testified, that that level in a patient like Ms. Knight shows that she was over-anticoagulated at the time of her bleed.

So, again, additional support for the opinions that Dr. Ashhab opined on and, again, comes from the defendant's own documents, their own studies, their own scientists.

THE COURT: What else does he rely upon, then, does Dr. Ashhab rely on?

MR. CHILDERS: He -- sorry, Your Honor.

He basically relies on that measurement being three

half-lifes after she came in the hospital with the bleed and extrapolates that it was three half-lifes higher than that when she came in.

The fact that he's a gastroenterologist, let me address that if I could, Your Honor. He's also a board-certified internist. And as a gastroenterologist and an internist, he treats patients who have gastrointestinal bleeds that are caused by anticoagulants. He knows how to assess the level of anticoagulation in these patients because that's the patient he treats.

To discount his ability to utilize a coagulation test in a bleeding patient because he doesn't prescribe Pradaxa I think would be improper. He treats the patients for whom these bleeds happen because of the anticoagulation. So I think he's absolutely the doctor who has to be the one on the front line interpreting these tests when they matter most to patients in the U.S.

THE COURT: Well, can you explain any more about what sort of clinical judgment he's exercising? Or is it simply that he would take an aPTT at a given moment and then determine when Pradaxa was last given?

MR. CHILDERS: Correct.

THE COURT: And then from that, he would say if they had a bleed before, it must have been that they were over-anticoagulated?

MR. CHILDERS: I don't think that -- honestly I don't think he said because she had the bleed, she was over-anticoagulated. I think he said that is evidence of her anticoagulation, and that's why she did have the bleed is because he believes she was over-anticoagulated. But that certainly goes into his assessment.

He's a doctor who treats patients for the very type of bleed that Ms. Knight had on a daily basis, and that is how he would evaluate his own patient to decide -- if a patient like this came in on warfarin, he would have been able to test specifically and reverse it if he needed to. He testified he can't do that for patients on Pradaxa, so he has to use the tools he is given, one of which is to look at aPTT and try to figure out how long it's been since their last dose and figure out if they're over-anticoagulated.

THE COURT: Okay.

MR. CHILDERS: So let me see.

Design defect, I believe -- do you have any other questions, Your Honor, about the failure to warn?

THE COURT: Well, we'll get to this later, but let's talk at least briefly about the other proximate cause issue they raise, which is that Dr. Ashhab apparently can only say that from the medical records it seems that the doctor is treating her after this bleed was repaired, and admittedly it was repaired satisfactorily. I don't think anybody questions

that. She didn't have another one.

But that somehow she didn't bounce back, that it took some unstated or unspecified toll on her, and that over the course of the next several months in and out of the hospital, she died of a heart attack.

But I've got to tell you, that doesn't -- given this woman's overall condition, that is pretty weak.

MR. CHILDERS: Your Honor, on that point, he relied on the fact that she wasn't just hospitalized for a few days and went home. She had to be put into a long-term treatment facility there at the same hospital because of the de-bility that was caused by the bleed. She stayed hospitalized or in that unit for three weeks.

She then had to have home health care, who -- for another several weeks -- testified that it took that long for her to get basically to where they just couldn't make her any better. It's not that she was better, but they couldn't do anything else for her.

And he relied on the testimony of Dr. Abdelgaber, who said she kept coming back in each time complaining she had not gotten better from the time of the bleed. And he agreed that each time she came into the hospital or came to see him, that was the same complaint, that she wasn't getting any better, and that he observed she wasn't getting any better, and that that eventually led to her death. I believe you can rely on

that testimony.

And then the issue as to -- I believe that what Mr. Richmond said was, well, Dr. Ashhab just didn't unpack that opinion well enough for us. If you look at the deposition transcript, which is attached in its entirety, he wasn't asked that question until the very end by the defendant. And once he gave his bases for his opinion, they said no more questions. They didn't ask him to unpack it because they didn't want him to unpack it.

It's not up to him to answer questions that aren't asked. He has to be asked questions at a deposition in order to answer them. That literally was the last line of questioning, and then the deposition stopped without asking him to explain any further what he had said.

So I do believe not only is his opinion based on the records he looked at, but it is also based on the testimony of Dr. Abdelgaber, who was the primary care physician, who treated her throughout the course and up to the time of her death in the beginning of September.

So I believe there certainly is adequate evidence for failure to warn on those two issues we talked about and also the proximate cause from not only Dr. Ashhab, but she wouldn't have even been on Pradaxa had she been warned don't take this if you're taking these other medications, or had her doctor been warned of that at the time she started the medication.

May I move to design defect?

THE COURT: Yes.

MR. CHILDERS: Again, Your Honor, on design defect, plaintiffs have to show an alternative, safer way to provide Pradaxa to patients in this state, in West Virginia. Again, we believe that the foreign labels should be allowed for that because they show exactly -- again, these aren't theoretical issues that we have hired some expert to come up with and say this is how the label should read. These are the labels that Boehringer is actually giving to physicians in the rest of the world. And the argument here is they know how to do this, they know how to make this drug safer for patients like Betty Knight, and all they have to do is use that same information here in the United States.

The issue about the antidote, Praxbind, you asked some questions about that. In plaintiffs' response, I believe it's pages 10 through 11 of the response to the motion for summary judgment, there is a timeline of the development of this reversal agent. And the antibody that eventually became Praxbind, the reversal agent, was made by Boehringer, not by an outside company, in 2002. And the testimony, again by Boehringer's own people, was that it was put in the freezer, and nobody touched it again until 2008.

And then the question then moved to -- or the presentation then moved to Judge Land's order from the

Chambers case, who I assume is not related to Your Honor.

THE COURT: I don't think so.

MR. CHILDERS: And if you look in Judge Land's opinion, there is two -- there is at least -- there are several distinctions here.

First of all, there was no failure to warn claim that was premised on the lack of a reversal agent in that case. It's a different case, and for different reasons, plaintiff didn't pursue failure to warn based on lack of information about adequate reversal of Pradaxa. So that's one very clear distinction that we have in the present case.

In the present case we have shown, Your Honor, in our brief on page 10 at footnote 36, Boehringer's own scientist, Dr. Paul Reilly, wrote an e-mail back in 2012 where he said the information that we provide to physicians in our label, where it says we don't have a reversal agent, but here are some ways you can fix it, is inadequate.

That's not my language. He actually wrote that, I believe this is inadequate. Clearly that is evidence of the potential inadequacy in the information that is provided to physicians as it relates to the reversibility.

But getting back to the reversal agent, as Your Honor asked the questions, I think it became clear, Pradaxa was approved in October of 2010 for sale in the United States. By 2008, two years -- actually more than two years before because

it was the beginning of 2008, Boehringer had already proved internally they could reverse Pradaxa with Praxbind. They knew this more than two years before they got Pradaxa approved. They did not approach the FDA to start getting the approval process for Praxbind until 2011, after Pradaxa had already come on the market.

Had that information been given to FDA, I can't say what they would or would not have done, but at least they would have known there is a way to reverse this particular product which we know is going to cause bleeds in patients. And that information I think is more similar to what you alluded to from Judge Fallon in the Xarelto claims, where he noted the company knew how to do this. They knew how to reverse the Xarelto drug before the time they put it on the market, but they didn't do what they should have done to have a reversal at the time. Same exact issue here. It's the same exact issue because the timing is more than two years before approval.

THE COURT: Isn't that, though, exactly what Judge Land looked at, too?

MR. CHILDERS: He did, and respectfully, as much as I respect Judge Land, I believe he got that wrong on that particular issue. But, again, he also was looking at it in terms of not having a failure to warn claim that was based at all on that issue.

And what we've argued here, and I think this is accurate, Your Honor, is just making a reversal agent wasn't the only way to deal with the issue about how to treat a patient who was bleeding on Pradaxa, how to get the Pradaxa out of their system, how to make it so that Pradaxa is not contributing and making that bleed worse.

THE COURT: Yeah, it's not clear to me what your evidence is, if you were permitted to develop this at trial, that there was a feasible, safer alternative at the time of FDA approval here that would have made Praxbind unnecessary. There was some feasible alternative drug or treatment that could provide this sort of reversal antidote.

If it's not Praxbind --

MR. CHILDERS: Sure, and that's a tough spot, and I'll agree with Your Honor on that.

But we base that on the fact that there is specific information that is put in the label about what to do if a patient comes in and they're bleeding, which the company agrees they actually haven't tested it to see if any of it works, and then their own scientist says I think it's actually inadequate to tell physicians this.

So I believe that is a design defect in the drug itself. Giving bad information to physicians about how to treat it is just as bad as not telling them the right way to treat it. Especially with someone like Ms. Knight, who is

having a bleed, and there is not something that can be done to slow it down in a way that could be done if they were given the proper information.

In addition to that --

THE COURT: Well, let me ask you about this.

MR. CHILDERS: Yes, sir.

THE COURT: Frankly this kind of just occurred to me because of perhaps the way you just said that.

So I know that she came in with gastrointestinal discomfort, and I guess she was starting to see blood in her stool, maybe it was getting worse.

MR. CHILDERS: Yes, Your Honor.

THE COURT: How long was she in the hospital before they surgically repaired the wound; do you remember?

MR. CHILDERS: It was one or two days. I can't remember specifically standing here, but I know it wasn't more than one or two days before the surgery was done.

She stayed in the hospital five days total before they moved her to the --

THE COURT: Well, I'm just wondering, then. So assuming that there was a reversal agent available then, what's your evidence that a reversal agent would have made the difference?

MR. CHILDERS: She may not have had to have surgery at all had she stopped bleeding because of the reversal agent,

Your Honor.

THE COURT: Well, it does seem to me that's perhaps a possibility, but fairly speculative. I mean, Dr. Ashhab described this type of GI bleed and said it's kind of common. I don't know that he discussed it any more really than that and the fact that it was repaired.

So it occurs to me that it's not clear what the evidence is that had there been a reversal agent available, it would have --

MR. CHILDERS: Sure. So -- if I may.

THE COURT: Yeah.

MR. CHILDERS: I think we attached the articles that were written by the company about the reversal agent. And it's pronounced idarucizumab, and I know that because I asked Dr. Reilly at his deposition. That is Praxbind.

And what it says is that it reverses the anticoagulant effect of Pradaxa within minutes. So it's not a matter of it takes several hours or it takes a couple days. It literally happens in minutes, and that's the evidence that Dr. Ashhab relies on to say that would have either lessened the bleed or made it last a less amount of time.

THE COURT: Okay.

MR. CHILDERS: Back to the warning issue, design defect, there is not one word in the patient medication guide that was given to Ms. Knight that tells her there's no way to

reverse Pradaxa. That's not included, still to this day is not included, and so I believe that is clearly a claim that should go to the jury.

THE COURT: Where is it that the defendant points to?

MR. CHILDERS: It's in the -- I'm sorry, Your Honor?

THE COURT: Where is it that the defendant points to in the --

MR. CHILDERS: In the label, the physician label, but not in the patient medication guide that would have gone to Ms. Knight or any patient.

And then as far as proximate cause, again, Your Honor, Dr. Ashhab testified that not having a way to reverse the drug did cause her bleed to last longer than it would have otherwise lasted.

Did you have any questions for me?

In regard to Dr. Ashhab, I think this is fairly well covered, the only guesstimates he made were trying to give an exact number. He can't do that, nobody can do that. But he gave an opinion that was based in medicine, based on his care and treatment of patients, and based on his review of what the company tells him as to how to measure the anticoagulant effect of Pradaxa.

THE COURT: Which includes a reference to relying upon the aPTT if there isn't something better.

MR. CHILDERS: So -- and if I could, Your Honor.

It says ECT is better, ecarin clotting time. No doctor that we have talked to, whether it be expert or otherwise, has ever used the ecarin clotting time. In fact, ecarin is taken from a snake. It's called a Russell's viper. They milk the venom out of this snake to get the reagent that is used in order to perform an ecarin clotting time test.

Having that in the label is -- I don't know why it's in the label because nobody ever uses it. aPTT is routinely used. If you or I were to go into the hospital, and we were bleeding, they would run that test on us whether we are on an anticoagulant or not. The problem is it's just not exact. An aPTT can give you an estimate, which is what the label says, but it can't give you an exact number.

And that comes back again to failure to warn because there is a test that will give a precise number to a doctor, the dTT, diluted thrombin time. And that, again, is not contained in the label. It's not contained in the patient medication guide. It's not contained in any information given to physicians in the United States, but it is contained in the information given to all doctors in the rest of the world.

THE COURT: So that's BI's recommended way of determining your Pradaxa blood concentration?

MR. CHILDERS: Yes. In fact, that's what they tell doctors is the preferred way to measure it when you look at the labels in those other countries.

And they tell them the same thing there about aPTT as they say here, which is it's an approximation, but dTT gives you an accurate assessment of the actual anticoagulant activity of Pradaxa in that patient or the blood level in that patient.

I believe that I've covered most of what I wanted to cover for Dr. Ashhab. I think we've provided enough information.

The only other thing I wanted to cover, if I could, on the foreign labeling, Your Honor, Mr. Imbroscio said that because Ms. Knight was on a half dose, she -- I wasn't quite sure I understood, but that she shouldn't have been over-anticoagulated because it's a half dose. But he also told Your Honor that the reason she is on a half dose is because that was the information that was modeled from the 150 dose to say that a patient like her, with severe renal impairment, is going to have the same amount of Pradaxa in her system.

So just as you can be over-anticoagulated on the 150-milligram dose if you have normal kidney function, you can be over-anticoagulated on the 75-milligram dose when you have severe renal impairment. The missing information here, the key is tell doctors how to figure that out. And that is, again, where we differ on what is at issue in this case.

We don't have any intent to come in here and say that

different doses were approved in other countries and, therefore, Boehringer did something wrong. Our intent here is to show there is information that can be provided to doctors that will help them to better treat their patients to make sure that, as best they can, they can avoid a bleed, but that the company doesn't share that here in the U.S. even though it does in the rest of the world.

If you have any other questions, I'm happy --

THE COURT: No. Thank you.

MR. CHILDERS: Thank you, Your Honor.

THE COURT: All right. Replies?

MR. HUDSON: If I may, Your Honor.

Your Honor, if -- can we come back to Dr. Ashhab and the chart?

THE COURT: Sure.

MR. HUDSON: Okay. And so we've pasted into BI's motion to exclude Dr. Ashhab the chart with the handwriting on it.

THE COURT: Right.

MR. HUDSON: If that is unclear at all, I think maybe a better copy is attached as Exhibit 10 to --

THE COURT: Where it is part of the label?

MR. HUDSON: Yes.

THE COURT: All right.

MR. HUDSON: -- the opposition to the plaintiffs'

motion for summary judgment, so it's got the full label there.

But Dr. Ashhab was asked about that graph because he said, okay, well, I see 47 aPTT. So I take that to mean then when she took Pradaxa 36 hours earlier, or roughly thereabouts, her blood plasma concentrations must have been higher, and ergo she must have been over-anticoagulated.

But if you look at Figure 4, which is from the label, that chart is average aPTT time courses for people with different levels of renal function over time, and his little dot is actually on -- for people with good renal function. The graph for people with impaired renal function is two lines higher, and those would be the aPTT average time courses that you would expect to see in a patient with renal impairment, 15 to 30 milliliters per minute for creatinine clearance.

So that's not -- and the aPTT, I think it's become clear, it's subjective. It's quantitative. Excuse me. It's qualitative, it's not quantitative. It will tell you is this person anticoagulated?

So -- but what that label says is, okay, here's the data from the RE-LY trial, people taking Pradaxa. Here's the average aPTT time course. He picked a number, the 47, 36 hours later, which if you look at Ms. Knight, that doesn't say anything that would suggest she was over-anticoagulated.

I mean, the graph is self-explanatory. So if you can look at the graph, that really undercuts the notion that that

47 aPTT suggests anything about her being over-anticoagulated.

Was she anticoagulated still? Maybe, but that gets into the half-life. Because Dr. Ashhab thought, and I think counsel was discussing Dr. Ashhab's statements where he said, well, that's like three half-lifes later, 12-hour half-lifes. But Dr. Ashhab didn't look at the label.

Exhibit 10 to the opposition motion, Table 3 under Section 12.3, pharmacokinetics, sets forth the half-life of the medicine in people based on their renal function. In people with severe renal impairment, which is creatinine clearance from 15 to 30 milliliters per minute, the half-life that is in the chart is T one-half slash hour, 27 hours.

THE COURT: So explain that to me, then.

MR. HUDSON: It means the label is telling doctors that in a person -- in a person with impaired renal function, so much that their kidneys are processing things such that their creatinine clearance rate is --

THE COURT: Much slower.

MR. HUDSON: -- less than 30 -- yeah, it's slower, you're getting stuff out slower -- the half-life to get the drug out is 27 hours.

And so --

THE COURT: Instead of 12.

MR. HUDSON: Ergo, that's why you take a lower dose. Dr. Ashhab, he testified, well, that's three 12-hour

half-lifes later. Surely her aPTT should have been lower.

And so when you take his guesstimates, well, you know, maybe 80, maybe 90, 100, and you say, well, okay, you can't quantify any level of over-anticoagulation because you don't have that measurement, so I'm not going to hold that against you, you gotta look at, well, what is he basing his over-anticoagulation opinion on to begin with? And if you just look at the label, he's just wrong.

THE COURT: Okay.

MR. HUDSON: All right. I'm going to circle back now.

Plaintiffs' counsel started talking about P-gp inhibitors as the other aspect of their failure to warn claim. And, again, I'll come back to what I mentioned earlier where there's got to be evidence to show that a different warning would have made a difference. And there's no testimony from any physician that was associated with Ms. Knight in any way that, one, they weren't aware of that after the label was changed; or, two, that they would have done anything different with respect to Ms. Knight.

THE COURT: You're talking about just for those inhibitors?

MR. HUDSON: Correct.

THE COURT: All right.

MR. HUDSON: Correct.

So in terms of the record, they've got an expert

saying, well, BI should have done this. But in terms of the testimony and the record before this court, and looking at, well, had BI done what Dr. Ashhab should have done, would that have made a difference, there is nothing in the record to support that. There is no testimony on it.

In terms of the children's testimony about Ms. Knight and the labels, I think it's pretty clear there is no evidence that she read the Pradaxa labels, the Pradaxa medication guide. That's tabs 10 and 11 to our motion. It speaks for itself, so I won't speak more to that.

Plaintiffs' counsel mentioned a couple of times the importance of the EU labeling with respect to alternative feasible design. And I want to hit that a little bit because the plaintiffs don't have to have -- they don't have to bring in the EU labeling or the company core data sheet or anything that talks about how the company warns in different countries to propose to a jury what a different warning should have been.

They have the RE-LY data. They've got the studies. But, you know, the notion of them wanting to have an alternative feasible design for a warning, that is -- that is a creative argument to kind of back-door in this foreign labeling as, well, this is what you could have done.

THE COURT: Well, I don't follow you. Why is that somehow inappropriate?

I mean, you've said you agree that they could rely upon other medical studies to say that the warning label should have quantified the increased risk. But in addition to that, if they've got evidence that BI essentially said in some forum that here's the way we quantify this increased risk, why is that not also admissible?

MR. HUDSON: For all of the reasons that Mr. Imbroscio said. I just wanted to point out that this notion of alternative feasible design in a failure to warn context is creative in terms of an effort to get in a warning from somewhere else and saying, see, they could have done this.

I think the Nease case and Judge Goodwin's case, you know, talk about alternative feasible design in the design defect context --

THE COURT: Right.

MR. HUDSON: -- not in failure to warn.

Failure to warn is when you have your experts come in and say this is what the plaintiff -- this is what the company should have warned about, and this is why.

THE COURT: Why is this any different than to say your failure to warn is that we can show you had knowledge of the quantification of these risks and actually provided warnings to that effect to somebody else?

MR. HUDSON: And that's all what Mr. Imbroscio covered already in terms of the foreign labeling. But they don't have

that -- the notion that, well, we have to do it because it's an alternative feasible design, that's not an element of a failure to warn claim. So the notion that they have to do that to meet some element is not present.

The notion that -- I just gotta say it -- they put the antibodies in the freezer, the fact that you keep lab materials in a freezer being used against us is -- I think that kind of underscores Judge Land's conclusion that no reasonable juror could conclude that, you know, you just put something that you knew worked in the freezer.

THE COURT: Well, I agree that's a bit of a pejorative way of characterizing it. But what about the other evidence that plaintiffs pointed to about the timing of some of the studies that you all were doing? And I don't recall the precise study or date, I'm sure you saw it referred to, but it was pretty close to the time that Pradaxa came out.

So what about that?

MR. HUDSON: It doesn't impact anything I've talked about earlier in terms of Judge Land's addressing the same information, saying no reasonable juror could reach that conclusion. The company acted expeditiously to get this approved. And then you've got the preemption layer on it as well, and then you've got the design defect element as well in terms of causation.

The plaintiffs said that their -- you know, part of

their failure to warn claim is not only the absence of a reversal agent, but the absence of effective ways to reverse the medicine, reversal agent aside. Dr. Ashhab, he doesn't offer any opinion on that, and his report is attached to our pleadings.

And he offers no opinion that had Praxbind been available, her bleed may -- he opines that her bleed would not have been as bad, but he offers no opinion that her bleed would not have been as bad had better, other reversal agents been available.

So these are -- you know, I am hearing --

THE COURT: I guess as maybe counsel perhaps even conceded, they really don't have evidence that there was a feasible alternative design in the form of some other treatment to reverse Praxbind -- or Pradaxa.

MR. HUDSON: Correct. There is nothing -- again, it comes back to, okay, where is the proximate cause problem for Ms. Knight? There are no expert opinions on that.

And Dr. Ashhab's report is in the record now, and there were some questions asked about what Dr. Ashhab explained in terms of his -- the nexus between the bleed and the death in the late summer or fall. I mean, Dr. Ashhab's report doesn't tie it together.

THE COURT: Well, what about what -- he quoted the treating doctor, and I forget which one he was --

MR. HUDSON: Uh-huh.

THE COURT: -- the treating doctor who apparently said he treated her, followed her up in the hospital afterward, and she was -- that once they repaired the bleed, she remained in the hospital, went to I guess a transitional care unit perhaps or something there, skilled nursing at the hospital for three weeks. And that I guess perhaps -- I don't think I'm overstating it, but that that doctor said, yes, this bleed caused her to have such a setback, and failure to recover from this bleed contributed to her having a heart attack.

I mean, that's pretty much what he said with or without Ashhab --

MR. HUDSON: I think Dr. Abdelgaber's testimony is not quite so strong.

THE COURT: Okay.

MR. HUDSON: But I'm not -- as attorney Childers said, that's in the record, so I'm not going to try to characterize that one because it says what it says.

THE COURT: Okay.

MR. HUDSON: But I'd ask the Court to take a look at that. Because earlier you asked me is it more of she's just not bouncing back, and I said it was. And as I've read that transcript -- and I took that deposition, although it's been a couple of years.

THE COURT: Okay.

MR. HUDSON: My recollection is he does not offer that sort of causation opinion.

THE COURT: Okay.

MR. HUDSON: And then just briefly on ecarin clotting time and direct thrombin time. We're being criticized for ecarin clotting time. We're being admonished for not having direct thrombin time available. But, again, where does this tie into Ms. Knight? Dr. Ashhab doesn't offer any opinions that this would have had any impact on her care or her outcome whatsoever.

THE COURT: Didn't Dr. MacFarland testify that if there had been an identified method for testing to determine Pradaxa blood concentration, she would have used it?

MR. HUDSON: She said sure.

THE COURT: And plaintiff has evidence that you all know of a way to do that and told European doctors how to do it. So why isn't that enough at least to get that issue to the jury?

MR. HUDSON: Well, I guess because it comes back to Dr. Ashhab and him saying she's over-anticoagulated based on what he looked at in the label. And I would ask the Court's indulgence in taking a hard look at that label --

THE COURT: I will do it.

MR. HUDSON: -- and what he relied on.

THE COURT: The last thing I'll ask you about is this

more recent chart that plaintiffs included in their reply -- or response, rather, I guess, on the blood concentration levels, the chart that shows aPTT scores compared to Pradaxa concentration.

As I understand it, they contend that BI admits that if you have a Pradaxa concentration level exceeding 200, that you're at significantly increased risk of bleeding. And that the aPTT scores depicted on this chart from that study reflect that many are around that 50 level, which is close to the 47 that was measured here.

MR. HUDSON: And forgive me, but could you repeat -- where is that at in your file?

THE COURT: Max will tell us. It's in plaintiffs' response to your motion No. 6.

THE LAW CLERK: Exhibit 5.

THE COURT: And it's on page 12 of their response.

Let's see. It's Exhibit 5?

MR. HUDSON: And is this the motion for summary judgment?

THE COURT: No, this is the plaintiffs' response to your motion No. 6 to exclude evidence regarding plasma concentration levels.

THE LAW CLERK: And it's Exhibit 17, not 5. Sorry.

THE COURT: It's on page 12 of the response.

MR. HUDSON: If it's okay with Your Honor, I'll let

Mr. --

THE COURT: Take a look at it. I'll give you a chance to come back to that or now if you --

MR. IMBROSCIO: I'll give it a shot.

THE COURT: Okay.

MR. IMBROSCIO: And your question again, Your Honor? I want to make sure I understand it.

THE COURT: All right. So according to this chart, which they attribute to your client, it shows that with aPTT times of around 50 seconds, they could have -- as it refers to patients like Betty Knight, they have observed Pradaxa levels that are very high and that exceed 200 and even go up and exceed as high as 400.

So I guess what that seems to say is that with an aPTT in the vicinity of 50, which she had 47, you may still have very high Pradaxa concentration levels, and very high at points 200 or more or even up to 400 that are consistent with what you all have identified as being a significantly increased risk of bleed.

MR. IMBROSCIO: Yeah, I think it shows two points.

One is, to Mr. Hudson's point earlier, aPTT is at best an approximation, which we've said from the very beginning. I think what it probably means is that for the renally impaired, it's probably less of a good indication. Because when you look, there is actually a lot more dots in that chart that

would suggest relatively lower concentrations than the higher ones you just mentioned.

And so I think it goes to the level of the approximation, which again goes, I would suggest, back to the speculation point. That there is -- there is some evidence, but there's no reason that I've seen to think that Mrs. Knight is one of these dots on the right-hand side versus a dot on the left-hand side of that column.

THE COURT: Okay. I guess I sort of understand your point, and I agree.

MR. IMBROSCIO: Yeah.

THE COURT: But to me, it's something that the experts could rely upon even though they may have different interpretations or applications of the chart.

As I understand it, this just came out, and so Dr. Ashhab did not have this available and, therefore, did not rely upon it in his own --

MR. IMBROSCIO: He certainly didn't rely on it. What I'm not sure is whether this data was in the many, many internal documents and reports that were -- it just got published recently, but I suspect this probably comes out of data that was in their control.

THE COURT: I gotcha.

MR. IMBROSCIO: If I may, just on one factual issue on the reversal agent.

There was a suggestion that Praxbind was discovered and put on the shelf in 2002. Setting aside the put on the shelf parameter, that is just not correct. What was developed in 2002 as part of the normal drug development process were what are called polyclonal antibodies. You would never give a polyclonal antibody to a human being.

When this idea arose in late '08, the first quarter of '09 for potential -- using the antibody as an antidote, which was really a relatively unique idea, they pulled the old polyclonal antibodies from the freezer that they had developed as part of the process to test whether this would even work, and they were able to test a bunch of them, and at least for some of them it looked like it might work.

That's when they went off into the process of creating a monoclonal humanized antibody, which is a fairly difficult process. That took place in '09, into late '09 I believe, and that's what kicked off the development process. And so that really began in the late part of '09, ultimately was tested through the, you know, 2010, 2013 period, 2014, and then it was approved in 2015. Just so the record is clear.

THE COURT: Okay. Thank you.

MR. IMBROSCIO: Thank you, Your Honor.

THE COURT: All right. Mr. Childers, let me ask you to respond to one thing that Mr. Hudson brought up very specifically in his reply, and that is with respect to Dr.

Ashhab and his use of the 12-hour half-life.

MR. CHILDERS: Yes.

THE COURT: I think I didn't understand before that the label says that if you've got the type of conditions that she had, severe renal impairment, perhaps other things, that the half-life is not 12 hours as Dr. Ashhab assumed or believed, but rather a much longer period.

MR. CHILDERS: I can't quote to you the half-life, so I'm not sure -- I know that what we measure is by trough level and peak level.

THE COURT: I don't know what that means, but I --

MR. CHILDERS: So the trough level, which is usually what is measured to try to determine how high is the level, when you're looking for whether or not they are over 200 nanograms per milliliter, that is trough level, which means right before you take your next dose.

So that is a 12-hour --

THE COURT: So when you say trough, you're talking about the lowest point, which is presumably what you reach the latest you can be from taking the medication before you take the next dose?

MR. CHILDERS: Correct.

And the reason it's measured that way, as I understand it, is people's peak time just varies, but the trough time is always right before you take your next dose.

THE COURT: Okay.

MR. CHILDERS: If I could address this issue, though, about --

THE COURT: Well, now say this again, though, about your response now that I -- I was focused on this explanation of what trough level meant.

So are you aware of the provision in the label that the defendant cited where Mr. Hudson says essentially it tells you, the doctor, on the label that if you are a person with severe renal impairment, your half-life time is much longer than 12 hours; in fact, 27 hours?

And as I recall, Dr. Ashhab was pretty clear in repeating himself that 12-hour half-life, coming down three times in the process of 36 to the point of the 47 aPTT score.

MR. CHILDERS: I can't quote to you -- I know that as your kidney function decreases, half-life time does increase. I don't think it's extraordinarily increased, and that's the argument that they always make as to why they don't need a reversal agent because they claim Pradaxa just gets out of your system so fast.

But if I could -- I did want to point out that chart. Dr. Ashhab didn't rely on this chart in coming to his opinion. And if you look at the chart, it tells you -- these are simulations. These aren't from real patients, and there's a very good reason for that. There weren't any patients in the

RE-LY trial who had creatinine clearance as low as Ms. Knight.

THE COURT: They were excluded from the trial?

MR. CHILDERS: That's right. So they can't come in and say, well, this is what a patient would have. That's a guesstimate. That's a model.

What we have now is they actually finally looked at patients like Ms. Knight, and what we see is the chart that they just published, which is it's bunched up around 50 and goes up to not 400, but 700.

So, you know, they showed him that chart. He said, yeah, I can see what it says, but he didn't rely on that for his opinion. He relied on the aPTT measurement that he got and how he would treat a patient in that same situation if they came in bleeding and needed treatment.

THE COURT: Okay.

MR. CHILDERS: But I would say to you that, again, these aren't real patients. These are just models that they made internally trying to guess what a 75-milligram dose would look like in a patient, because they never actually tested it in those patients before they put it in the label.

THE COURT: Okay. Very good. Thank you.

MR. CHILDERS: Thank you, Your Honor.

(Off-the-record discussion with Law Clerk.)

THE COURT: All right. I wanted finally to also take up the matter of the trial date, trial preparation and so

forth. So we'll jump to the recent motion filed by the plaintiffs, and I've seen the defendant's response.

Mr. Childers, I assume by your reply that this e-mail communication that was actually generated a few days ago, but only completed recently, is the only contact you've had with Dr. Ashhab?

MR. CHILDERS: No, Your Honor. I got contact that he was out of the country, and then we immediately -- may I?

THE COURT: Yes.

MR. CHILDERS: That was why we approached and sent the e-mail to Max --

THE COURT: Right.

MR. CHILDERS: -- and then filed the motion.

Once that motion was denied, I sent those specific questions to Dr. Ashhab because I understood Your Honor wanted to know that information.

THE COURT: Yes.

MR. CHILDERS: I didn't get a response until after the response had been filed.

THE COURT: Okay. And so that response, e-mail response you got from the doctor, that came through when?

MR. CHILDERS: Yesterday afternoon at 1:37, I believe.

THE COURT: Well, his answers to your questions -- your questions were right on track. Some of his answers left me guessing a little bit.

So, first, do you have a more direct and speedy way of communicating with him?

MR. CHILDERS: If I did, I promise you I would use it.

I didn't know -- just so I can give you some background, Your Honor. I was in trial with Mr. Richmond, and in fact I was in trial before Mr. Richmond starting in February. And shame on me, I assumed he would be the easiest of my experts to get here since he is from Charleston.

THE COURT: Right.

MR. CHILDERS: As soon as I got back from that trial, trying to figure out where he was was the first time I learned he was out of the country, and that's why we brought it to your attention, Your Honor.

THE COURT: Okay. Well, I guess I accept all that. I guess now my remaining question is whether, or if not, why not, he couldn't arrange just to come here for a few days to testify in this trial and go back.

I appreciate that you've laid out some of the logistical challenges he has. I don't minimize the difficulty it might be for him to leave where he is, travel to Jordan, get planes to here, get here, testify or whatever is necessary in this trial and then get back. But what wasn't clear to me was whether, in addition to that just being difficult, there was some other reason for him to be unavailable.

And I guess specifically I'm wondering if you can

communicate with him and find out if, as a result of the combination of his father's death and these religious holidays, this period of fasting, if that is something that, in order to observe, he has to remain there. I'd like him to tell us that, and I don't want to just assume it.

MR. CHILDERS: I'd be happy to ask that question.

THE COURT: Well, I think I'd like you to. I think I'd like you to ask him specifically why you couldn't make arrangements with him to take several days, if that's what it takes, to get him here.

You know, he's an expert witness. And I've always kind of taken the approach when I was a lawyer myself that, you know, when you hire an expert, they agree to be there for you in the case, and it takes a pretty unusual circumstance to justify their unavailability.

He may have it. I respect that, you know, his father is from another country, and he left to go tend to his father, and his father died a couple of months ago. He may have these responsibilities, which coupled with religious observance may be a reasonable basis to find that his unavailability is excusable. But I'd really like to pin that down and have you do that as quickly as possible.

Secondly, as part of this, you've represented that you folks have, I guess -- is it the Chambers case --

MR. CHILDERS: In August.

THE COURT: -- in August?

MR. CHILDERS: Yes, sir.

THE COURT: And is he a witness there?

MR. CHILDERS: No, sir. He's only an expert in this one case.

THE COURT: Oh, okay. I misunderstood. You've got that case.

MR. CHILDERS: I am lead counsel in that case, and so --

THE COURT: Well, I guess then in any event the other question would be, if he believes that he should be excused from being here for this trial, when he expects or can commit to either returning or making himself available by returning for a short period in order to testify at a trial or at an evidentiary deposition.

MR. CHILDERS: And my understanding from that e-mail exchange that I've attached, Your Honor, was that --

THE COURT: Yeah.

MR. CHILDERS: -- he was available beginning in August, that he would be finished with whatever he had to do there.

THE COURT: Okay.

MR. CHILDERS: Unfortunately that didn't work because I have to be in Georgia that month.

THE COURT: All right. Well, so I'm going to direct

that you make --

MR. CHILDERS: Yes, sir.

THE COURT: -- an effort for this communication to take place as quickly as possible.

I don't know if you can get a phone number or something for him. I would ask that if you have tried that, that you try again and see if there is some way of communicating to him that, in addition to answering these questions as quickly as possible, even if it's by e-mail, that the Court would appreciate a more direct means of communication so that we can resolve this one way or another.

And if I'm going to continue this case as a result of his unavailability, then I would expect you to make clear to him that whatever new trial date we pick, he either better be here or you're going to have to take his evidentiary deposition before or he's going to cost you your case.

MR. CHILDERS: I understand and completely agree with that.

THE COURT: So let me ask this. You all indicated in the -- well, first, you've tried two of these cases recently.

MR. CHILDERS: Yes, sir.

THE COURT: I know these are different trials. There are no doubt some material differences.

My understanding from the defense is they were both defense verdicts?

MR. CHILDERS: They were, Your Honor. The juries found liability, but not causation in both cases.

THE COURT: Okay. Found liability on failure to warn?

MR. CHILDERS: Failure to warn in the first case. And in Connecticut, there was a claim for failure to test, and they found liability on that in the second case.

THE COURT: Okay. And so the causation was -- were these death cases?

MR. CHILDERS: The first one was, Your Honor. The second one was a hospitalization case.

THE COURT: All right. So with respect to the wrongful death product liability case, the jury did not find that you had proven causation, that the --

MR. CHILDERS: That is what the verdict form said, Your Honor.

THE COURT: Okay. And then the other one you say was just personal injury, hospitalization --

MR. CHILDERS: Correct.

THE COURT: -- the bills and so forth?

MR. CHILDERS: That's correct.

THE COURT: Okay. How long did it take to try those cases?

MR. CHILDERS: The first case, excluding jury selection -- because I won't bore you with how long it takes in Connecticut to pick a jury -- four weeks of time in trial.

And the second one was three weeks of time in trial.

THE COURT: How long did it take you to put on your case in Connecticut?

MR. CHILDERS: I believe it was -- it was over two weeks in the first case. It was --

THE COURT: So ten workdays?

MR. CHILDERS: It may have been more than that in the first case, I'm trying to remember. It was, I believe, nine days in the second case, and then we gave -- maybe nine and a half in the second case.

THE COURT: So here when I got the pretrial order today, I noticed that first you've only got four live witnesses, four or five, and then you've listed deposition excerpts.

Do you think that your two recent cases are representative or indicative of what this case will require for you to put on your case fully?

MR. CHILDERS: I do believe it will, and we didn't actually have any dispute on that with the defendants.

One of the issues with the videotaped depositions is several of them are witnesses who were in German, and an issue that we had was that the defendants wanted them to have the German answer and then the translation played, and that just increases the amount of time that those depositions have to play in court.

THE COURT: And that will be true in this case?

MR. CHILDERS: I assume so, but I haven't -- I've just assumed that because that's what they insisted on in the first two cases.

THE COURT: All right.

MR. IMBROSCIO: If I may respond on a couple points, Your Honor.

THE COURT: Yes.

MR. IMBROSCIO: I was at both trials as well.

The first trial, there was no -- just to take them in reverse order, there was no testimony of German witnesses on videotape. The plaintiffs chose to read them in. In the second trial, I think it was a grand total of two witnesses where there would have been some German testimony. That was not a driving force here in the length of the trial.

I think it was eight days or eight and a half days for the second trial --

THE COURT: I'm sorry. Say that again.

MR. IMBROSCIO: I'm sorry.

I think eight and a half days for the plaintiffs' case in the second trial. I think it was from a Tuesday to a following Friday. We had some snow days, I think we had three or four snow days in the first trial.

But the larger point is there's actually very little testimony in the company depositions on the 75-milligram dose,

so there is arguably a case that there will be less testimony that would be relevant for this particular --

THE COURT: How long did it take you to put on your defense case in the other two?

MR. IMBROSCIO: I think we did it in three days, maybe -- was it three days? I think three days, maybe carried over to the fourth day some videotape.

THE COURT: All right. Do you have any reason to believe that it would be much different in this case?

MR. IMBROSCIO: I think we can do it -- we have three experts. I think we can do it even more expeditious -- we're getting better at this, and we can do it I think more quickly. I think that should be the same for both sides.

THE COURT: Okay. Well, then I'll be candid about part of this at least.

While I'm still anxious to find out what Dr. Ashhab has to say about when he can be available, I had no idea until Mr. Bell talked with my clerk Max, I guess in an e-mail first, about the problem with Dr. Ashhab, and I think in that maybe he indicated to Max that these cases have been taking four to five weeks when they've been tried, and they've been tried recently. And that presents two big problems for me.

You're scheduled to start June 4th or 5th, something like that. I have scheduled an overseas vacation with my whole family to start on Monday, June 25th, and I have great

reluctance in starting a trial on the 4th or 5th that may carry us into that period.

Secondly, that is also a very long time for a jury here. And I can tell you that when I reviewed the jury panel for -- I guess the current period probably started at the end of March, I get an awful lot of folks who are working or have other responsibilities who indicate that, you know, if they're involved in a lengthy trial, they're going to have a huge problem, and they all want to be excused.

And so there are a number who frankly I refuse to excuse them and simply say, if I've got a short trial, you know, maybe a day or two, which is kind of common especially for criminal cases, I would expect you to serve. If it is anything much longer than that, I'm not going to do that because, quite honestly, many of these people cannot financially afford to spend two or three weeks in a trial here where they're not being covered by their employers, and we only pay them a fairly nominal amount.

So if I'm going to have a trial of this length, I would expect to have more forewarning about it than I had on this one. I'm not going to fault you all. But if I had known in advance that this was possibly going to be a three-, four- or five-week trial, I probably could have taken steps to avoid both of these difficulties, both my own schedule as well as the problem with jurors.

I've had this come up before. And when we've had trials that were expected to be this type or this length, I've often sent out jury questionnaires very early explaining to people, without any identifying information, that they are on the list for a possible trial that could last for a period of weeks. And I explain to them, clear your schedule, start making arrangements to move anything that you can move, because I'm not going to be able to excuse everybody just because it's inconvenient or in some measure even a hardship to be a juror for that length of time. That would be impossible to do now for a trial set to start in about two and a half weeks.

So I tell you that only because that's going to be a factor in my evaluation of this. If I find Dr. Ashhab's excuse or his unavailability is reasonable, then I'm going to move this trial. Even if I don't find that excusable, and that there is some other arrangement that can be made, I'm just going to have to think about how we handle bringing in a jury when it sounds like there is a reasonable possibility, if not probability, that this trial is going to go past that point of difficulty for me.

So I don't know that I can tell you anything else yet. If you want any clarification or have a question about it, feel free to raise it right now. That's the best I can tell you.

What I would expect to do is to have Mr. Childers get back with us I would hope in a day or two. I mean, I don't know --

MR. CHILDERS: You may have seen, Your Honor, I also asked in that e-mail for him get back to me as soon as possible. And, again, I don't know what he's going through over there other than just what I've gotten from the e-mail.

THE COURT: I understand that.

MR. CHILDERS: So I am trying to respect --

THE COURT: I agree.

MR. CHILDERS: -- that as well for his family.

THE COURT: I mean, I have every reason to believe that you'll use your best efforts --

MR. CHILDERS: Yes, sir.

THE COURT: -- and just as soon as you can, let me know.

Mr. Hudson?

MR. HUDSON: Your Honor, I guess just two quick points.

One, given the travel difficulties, I mean, if it permitted us to keep the bracket we've got -- I mean, we told you in our opposition motion we've got the Chambers case in August, we've got another one in September. There's -- I know it's an inconvenience for Dr. Ashhab with what he's got going on, but it's an inconvenience for a tremendous number of

people to move this now here.

THE COURT: Sure.

MR. HUDSON: So we can go to London, we can go somewhere in Europe if he can get there. We can do a before trial deposition. You know, there are other options that we're willing to do, and I think we mentioned that in our brief, but I would reiterate them here to try to keep on track.

And then I guess in terms of the timing, you know, we can digest what the Court has talked about, and I know we'll be before you again on Monday for the pretrial and look at that.

THE COURT: Okay. That's the best we can do for now, then.

Have you all tried to settle this case? Have there been any meaningful discussions?

MR. HUDSON: We mediated it before --

MR. BELL: John Curry.

MR. HUDSON: -- John Curry.

THE COURT: How long ago was that?

MR. BELL: A couple weeks --

THE COURT: Oh, just a couple of weeks ago?

MR. BELL: Two or three weeks ago. And Mr. Childers was in trial, I believe, and tied up. I was there with another one of his partners, and we made true best efforts,

but it was really jammed up relatively quickly.

THE COURT: Pretty far apart?

MR. BELL: Apparently so. The last thing the plaintiffs came back with was bracket an attempt to shake things loose at the mediator's suggestion. And I understand the defendants weren't interested in that bracket, and it concluded I think right about lunchtime or so.

THE COURT: Well, all right. At this point I don't know that I can expect you to do anything else.

So I'll expect Mr. Childers to provide us with some response as quickly as possible. And then if that doesn't happen or it doesn't clarify things, then I'll see you back here on Monday.

MR. BELL: Your Honor, if I may?

THE COURT: Yes.

MR. BELL: I just want to thank you. I know when I originally took on the assignment as local counsel for Mr. Childers and his firm, I was fully engaged in the practice of law. And now that I'm semi-retired, my schedule is very limited, and I appreciate defense counsel and the Court's accommodation and understanding in that regard.

THE COURT: Certainly.

All right. Is there anything else that we need to take up while you're here?

MR. RICHMOND: No, Your Honor.

THE COURT: If not, thank you all for your presentations. We'll stand adjourned.

THE COURT SECURITY OFFICER: All rise. This honorable court will now stand in recess.

(Proceedings were concluded at 3:53 p.m.)

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CERTIFICATION:

I, Kathy L. Swinhart, CSR, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter as reported on May 15, 2018.

June 26, 2018
DATE

/s/ Kathy L. Swinhart
KATHY L. SWINHART, CSR